DATOSPIR MICRO

SPIROMETER

USER MANUAL

511-A00-MU2 • REV. 1.04

Sibelmed®

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DECLARATION OF CONFORMITY

The **DATOSPIR MICRO Spirometer** has been designed by the **SIBEL S.A. R&D&i** Department, with the cooperation of the **Hospital de la Santa Creu y Sant Pau Pulmonary Function Laboratory in Barcelona**, in line with the standardisation criteria of International Institutions: **ATS/ERS TASK FORCE** (American Thoracic Society/ European Respiratory Society) and National Institutions: **SEPAR** (Spanish Neumology and Thoracic Surgery Society).

The **DATOSPIR MICRO Spirometer** has been designed and manufactured according to the SIBEL S.A. Quality Manual, which is compliant with **EN 13485** and **ISO 9001** quality standards, with spirometers for peak espiratory flow (UNE EN 13826), as well as **European Directive 93/42/EEC concerning Medical Devices**. According to this Directive, the equipment is **Class IIa**. It is also compliant with Electrical Safety standards **EN 60601.1**, **EN 60601.1.1** and Electromagnetic Compatibility standard **EN 60601.1.2**, as indicated in APPENDIX 1 ELECTROMAGNETIC COMPATIBILITY.

CE 0318

COMPLIANT PRODUCT
93/42/EEC Medical Device Directive
Class II a

Revised
Date: August 2009

José Maria Plana
Technical Director

Approved
Date: August 2009

Carlos Recio
Sales Director

SAFETY

SPECIAL PRECAUTIONS

The DATOSPIR MICRO spirometer has been designed for use with the utmost safety. All operating instructions must be read before using the **DATOSPIR MICRO**. Not doing so may lead to injuries to the user or the patient and damage to equipment and/or accessories.

INTENDED USE

The spirometer measures and calculates a series of parameters related to the human respiratory function.
The spirometer is designed for use by medical staff and by the patient when supervised and instructed by a doctor.
The spirometer is not designed for use outdoors or under other conditions or using other power sources not indicated in this manual.

In hospital mode, the DATOSPIR MICRO is a complete spirometer and users may fully configure the instrument.

In home mode, patients may only switch the equipment on, blow and switch it off. The doctor must have previously configured this mode before prescribing use of the instrument.

EFFECTS ON PATIENTS USING THE SPIROMETER

The spirometry tests require patient cooperation.
Complete forced expiration is required to obtain significant patient FVC values. The doctor must assess the patient's capacity to undertake spirometry tests. Special attention must be paid to children, the elderly and the disabled.

LIMITATIONS OF USE. CONTRAINDICATIONS

An analysis of the results of a spirometry tests is not enough in itself to give a correct diagnosis of the patient's clinical condition.

The patient's records and any tests that the doctor believes necessary must therefore also be considered.

A doctor must interpret the tests and any treatment provided as a result.
The patient's symptoms must be taken into account by medical staff before any spirometric test is undertaken.

Acceptability of a test is the responsibility of the medical staff.

The spirometer must not be used when the validity of the results is likely to be jeopardised by external factors.

Patients to have suffered myocardial infarction during the past month are recommended not to take the test. In patients with thoracic or abdominal pain, oral or facial injuries, stress or dementia of any kind, the results may not be optimal and repeatable.

ELECTRICAL RISKS

Dot NOT remove the equipment casing. The device must only be serviced and repaired by skilled personnel. The contact with voltage inside the system may cause serious injury.

Do NOT use damaged accessories

Do NOT submerge the parts of the device in any liquid. THIS MAY CAUSE ELECTRIC SHOCKS.
Consult the equipment cleaning method in Chapter 8, Section 8.1. UPKEEP, PREVENTATIVE AND CORRECTIVE MAINTENANCE.

To ensure vital safety features under the EN 60601-1-1 standard, only equipment compliant with the electrical safety standards in force may be connected to this device. To connect Datospir Micro to a non medical equipment with earth conductor, it must be installed an aditional earth protective conductor to the non medical equipment.

The equipment must be stored and used within the temperature, pressure and humidity margins specified.

RISKS OF EXPLOSION

Do NOT use the equipment in the presence of anesthetics or inflammable gases. THIS MAY CAUSE AN EXPLOSION.

RISKS OF CONTAMINATION

Turbine transducer: To avoid the risk of contamination or cross infection, the turbine must be disinfected as indicated in this manual.

Mouthpieces: Reusable mouthpieces must also be disinfected. Disposable mouthpieces must not be reused.

Pulse oximeter finger clip: Although unlikely, the organisms can also be transmitted by pulse oximetry. Therefore, the pulse oximeter finger clip should be washed with each patient change using either soapy water or a glutaraldehyde solution (Instrunet type).

RISKS OF INTERFERENCE

This is an electronic product and, therefore, high frequency emissions may interfere with its correct use. Therefore, keep the spirometer away from products (radios, cellphones, etc.) that may generate interference.

REMOVAL OF WASTE FROM ELECTRICAL AND ELECTRONIC APPLIANCES BY DOMESTIC USERS IN THE EUROPEAN UNION

This symbol on the product indicates that you cannot dispose of the product with domestic waste.

However, any removal of this type of waste is the responsibility of the user and must be taken to a designated collection point for the recycling of electrical and electronic appliances. The separate recycling and collection of this waste at the time of

removal will help preserve natural resources and ensure that recycling protects your health and the environment. Should you require further information on the places where you can leave this waste for recycling, contact the local authorities in your town or city, the domestic waste management service or the distributor who sold you the product.

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1. INSTRUCTIONS FOR USE AND INSTALLATION

1.1 INTRODUCTION

The **DATOSPIR MICRO** spirometer is a compact device with a 2x16 screen (Model A) or a high-resolution graphic touch screen (Models B and C), depending on the model. It works with turbine-type transducers that can be connected to an external printer by USB. It can incorporate a module for pulse oximetry measurements (SpO_2).

Furthermore, using software (included depending on the model), it can be connected in real or deferred time to a PC for spirometric tests with PC support, to save completed tests or to transfer data via other means. It can be connected to the PC using an RS 232 cable, a Mini USB cable (included as standard) or by Bluetooth (optional).

The entire system is controlled by a microprocessor for the acquisition, calculation and presentation of alphanumeric and graphical data.

The **DATOSPIR MICRO** is available in a series of models, depending on the different options included, as indicated in detail below.

1.2 PRIOR OBSERVATIONS

This User Manual is for all models and options of the **DATOSPIR MICRO** spirometer. Therefore, only specific options or functions of the model available will be applicable in each case.
This spirometer has been manufactured using solid-state professional components under strict quality controls. However, accidents may occur during the transportation or storage of the equipment and it is therefore wise to initially check its condition and that of its accessories before installing them.

WARNING
SHOULD YOU DETECT ANY DAMAGE TO THE PACKAGING, CONTACT THE HAULIER AGENCY AND DISTRIBUTOR IMMEDIATELY BEFORE STARTING THE INSTALLATION. PACKAGING AND BAGS, ETC. MUST NOT BE DISPOSED OF UNTIL THE CORRECT WORKING ORDER OF THE EQUIPMENT HAS BEEN FULLY VERIFIED.

1.3 DATOSPIR MICRO SPIROMETER MODELS

The **DATOSPIR MICRO** spirometer series is made up of the following models, depending on the options included:

DATOSPIR MICRO A
DATOSPIR MICRO B
DATOSPIR MICRO C

The enclosed tables show the basic **standard** features of each model and all other **optional** parts and functions.
A model can be upgraded at any time by adding the corresponding parts. To do so, please contact the **SIBEL S.A.** Sales Department or your distributor.

The main feature differentiating Model A from Models B and C is its operating mode. Model A works with a 2-line screen in text mode and using 4 silicon keys. Models B and C work with a touch screen in graphic mode and using a pointer.

RELACIÓN DE CONTENIDO / PACKING LIST

CÓDIGO *CODE*	CANT. *QTY.*	DESCRIPCIÓN *DESCRIPTION*	MODELOS / *MODELS* A	B	C
511-A00-00_	1	**DATOSPIR MICRO MODELO / *MODEL*** **SN: 11A-**	o	o	o
511-AG0-000	1	CÓDIGO DESBLOQUEO (PUK) / PERSONAL UNBLOCKING KEY (PUK)	√	√	√
511-A21-040	1	PUNTERO / POINTER	---	√	√
510-121-060	51	BOQUILLA CARTÓN DESECHABLE / *DISPOSABLE MOUTHPIECE*	√	√	√
501-611-030	1	BOQUILLA DE PLASTICO / *PLASTIC MOUTHPIECE*	√	√	√
140-550-010	1	PINZA NASAL / *NOSE CLIP*	√	√	√
511-A11-090	1	GUIA RAPIDA DE USO MOD. A/ *MOD.A QUICK REFERENCE*	√	---	---
511-A21-090	1	GUIA RAPIDA DE USO MOD. B/C / *MOD.B/C QUICK REFERENCE*	---	√	√
305-600-030	1	CONEXIÓN PC - USB/ USB *PC CONNECTION LINK* (CABLE MINI USB B 5 PINES – USB A)	√	√	√
321-100-090	2	PILA AA 1.5V ALCALINA / *AA 1.5V ALKALINE BATTERY*	√	√	√
511-A30-000	1	TRANSDUCTOR TURBINA / *TURBINE TRANSDUCER*	√	√	√
511-AA0-002	1	MALETA DE TRANSPORTE / *CARRYING CASE*	√	√	√
511-AA0-001	1	CONEXIÓN PC – RS232 / *PC – RS232 CONNECTION LINK* (CABLE MINI USB)	√	√	√
511-A00-MU_	1	MANUAL DE USO / USER MANUAL	√	√	√
511-8F0-DM0		SOFTWARE ESPIROMETRÍA W-20 DEMO Compuesto por : *SPIROMETRY SOFTWARE W-20 Composed by:*	√	√	√
511-8FA	1	• SOFTWARE W-20 (CD)			
511-8F0-000	1	LICENCIA SOFTWARE ESPIROMETRÍA W-20 *SPIROMETRY LICENSE SOFTWARE W-20*	o	o	√
511-850-009	1	OPCIÓN PULSIOXIMETRIA SOFTWARE W-20 *PULSEOXIMETRY W-20 SOFTWARE OPTION*	---	o	o
511-850-011	1	OPCIÓN BRONCOCONSTRICCIÓN SOFTWARE W-20 *BRONCHOCONSTRICTION W-20 SOFTWARE OPTION*	o	o	o
511-AF0-000		OPCION IMPRESORA EXTERNA USB *USB EXTERNAL PRINTER OPTION*	√	o	√
305-600-040	1	CABLE MINI USB A 5 PINES – USB B			
511-AB0-000		MODULO PULSIOXIMETRIA (SENSOR FLEXIBLE) Compuesto por : *FLEX PULSEOXIMETRY MODULE Composed by:*			
511-AB0-001	1	• MODULO PULSIOXIMETRIA XPOD *XPOD PULSEOXIMETRY MODULE*	---	o	o
511-AB0-002	1	• SENSOR PULSIOXIMETRIA FLEXIBLE SPO_2 *FLEX PULSE OXIMETRY SPO_2 SENSOR*	---	o	o
365-216-061	1	• ADHESIVO SENSOR PULSIOXIMETRIA (25 u.) *PULSIOXYMETRY PROBE ADHESIVE (25 u.)*	---	o	o

RELACIÓN DE CONTENIDO / PACKING LIST

CÓDIGO ***CODE***	CANT. *QTY.*	**DESCRIPCIÓN** ***DESCRIPTION***	**A**	**B**	**C**
511-AJ0-000		MODULO PULSIOXIMETRIA (SENSOR PINZA) Compuesto por : *PULSEOXIMETRY MODULE (ARTICULATED SENSOR) Composed by:*			
511-AB0-001	1	• MODULO PULSIOXIMETRIA XPOD *XPOD PULSEOXIMETRY MODULE*	---	o	o
511-AJ0-001	1	• SENSOR PULSIOXIMETRIA PINZA SPO_2 ARTICULATED *PULSE OXIMETRY SPO_2 SENSOR*	---	o	o
511-AC0-000	1	MÓDULO BLUETOOTH *BLUETOOTH MODULE*	o	o	o
511-AL0-000	1	ADAPTADOR BLUETOOTH / BLUETOOTH ADAPTER	o	o	o
511-AL1-010	1	INSTRUCCIONES ADAPTADOR / ADAPTER INSTRUCTIONS	o	o	o
511-AD0-000	1	OPCIÓN FIRMWARE BRONCODILATACION *BRONCHODILATION FIRMWARE OPTION*	√	√	√
511-AE0-000	1	OPCIÓN FIRMWARE DIAGNOSTICO DIAGNOSTIC *FIRMWARE OPTION*	o	o	√
511-AH0-000	1	OPCIÓN FIRMWARE BASE DATOS – 1000 PRUEBAS *1000 TEST – DATA BASE FIRMWARE OPTION*	o	√	√
321-700-010	1	CARGADOR + 4 PILAS NiMh CHARGER + 4 BATTERY NiMh	o	o	o

WARNING

According to the different regulations, particularly the 93/42/EEC Medical Device Directive, electromedical devices should be verified and/or calibrated regularly to ensure reliable functions and the safety of patients, users and the environment.
As well as the routine DATOSPIR MICRO spirometer calibrations, its safety systems, adjustments and functions, etc. should undergo a general annual service and under no circumstances exceed an eighteen month period without having been serviced. These checks should also be made whenever the equipment is thought to be working incorrectly. These checks must be carried out by the manufacturer or by skilled technical personnel authorised by SIBEL S.A., according to the manufacturer's (SIBEL S.A) Verification and Adjustment Procedures.
All accessories and spare parts, etc. must be originals and are to be requested from the manufacturer or authorised distributor in order to ensure the correct working order of the spirometer.

MANUFACTURER'S LIABILITY

SIBEL S.A. is only liable for the safety, reliability and working order of this equipment if:

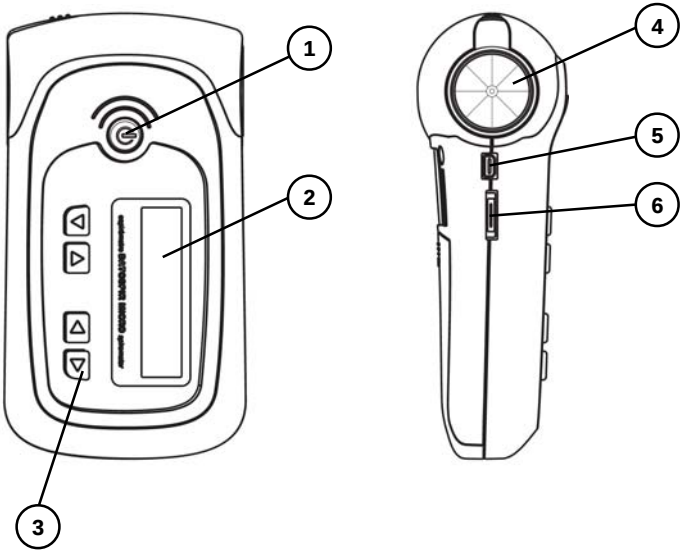
- The place where the equipment is installed or used is compliant with the requirements related to the IEC electrical installation and other applicable regulations.

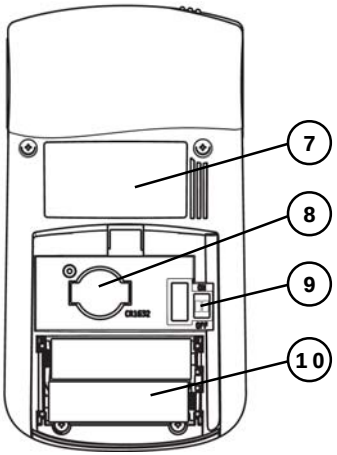
- All repairs, services and modifications inside and outside the guarantee period are carried out by SIBEL S.A. technical staff.

- The equipment is used by skilled staff according to the recommendations of this User Manual.

1.4 LAYOUT OF CONTROLS, PILOT LIGHTS AND CONNECTORS

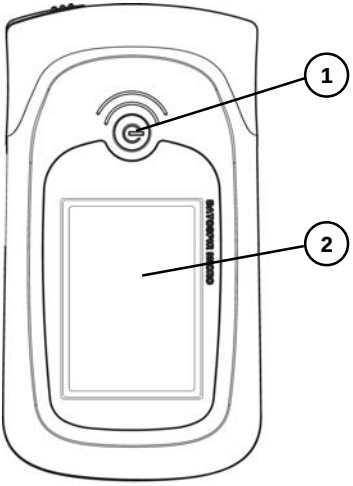
MODEL A

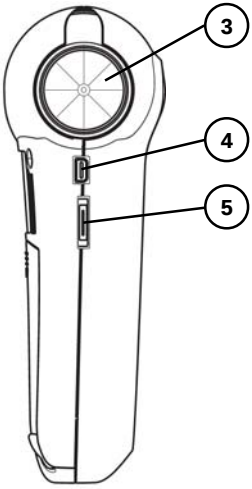


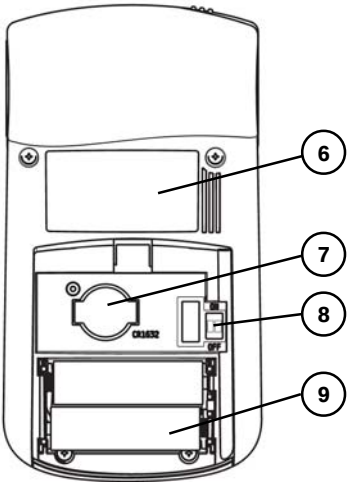


1- On/off button
2- Alphanumeric LCD display
3- Keypad
4- Turbine transducer
5- USB connection
6- RS·232 series connection
7- Specifications plate
8- Lithium battery (CR1632)
9- Firmware loading switch
10- Main batteries (2xAA 1.5V)

MODEL B / C







1- On/off button
2- Graphic LCD display
3- Turbine transducer
4- USB connection
5- RS·232 series connection
   SpO_2 Connection
6- Specifications plate
7- Lithium battery (CR1632)
8- Firmware loading switch
9- Main batteries (2xAA 1.5V)

1.5 INSTALLATION AND START-UP

DATOSPIR MICRO INSTALLATION

The **DATOSPIR MICRO** spirometer is **CLASS IIa** according to the criteria of the **93/42/EEC European Medical Device Directive** and, in line with the type of protection against electric shocks established by the **EN60601.1** standard, the equipment is rated as **CLASS IP type B**.

Batteries
The **DATOSPIR MICRO** spirometer works as standard using two AA 1.5 V batteries or optionally using rechargeable NiMh batteries (AA 1.2 V type).

WARNING:
Never try to recharge alkaline batteries. This would cause damage to both the batteries and the charger.

In both cases, the autonomy will depend on the quality of the batteries used. In Model A, 1.5 V alkaline batteries or with 2400 mAh rechargeable batteries will last for approximately 40 hours. Autonomy may drop by 50% when working via Bluetooth and USB connection to the PC will not use any batteries, given that the equipment is powered through the PC's USB port.
In models B and C, battery life will be smaller than model A. It will be directly affected by time that Lcd Backlight is on.
The charging time for rechargeable NiMh batteries will depend on the charger used.

To save power, the equipment includes an auto switch off system that turns the equipment off when not touched for **5 minutes**, except in main spirometry and pulsioximetry screens. In this case, the data on the screen is lost and the normal process must be followed to restart the equipment.

In models B and C, in order to save power, Lcd backlight will be switched off if the equipment is not used in 20 seconds.

WARNING:

When inserting the batteries for the first time or when changing them, the equipment may switch on automatically. This is normal and does not indicate any type of malfunctioning.

Atmospheric conditions
The atmospheric working conditions are:

- Atmospheric temperature between 10 and 40 ºC. (The American Thoracic Society recommends 17 to 40 ºC)
- Relative humidity below 75% (without condensation)
- Atmospheric pressure from 430 to 800 mmHg (from approx. 4500 to - 400 metres)

Location
Take care not to place the equipment where it could be splashed by water or other liquids or cover it with objects that prevent air from circulating around it while it is running.

Once the batteries have been inserted and the equipment is in a suitable place, it is ready to begin operating.

USB MODULE INSTALLATION

The equipment includes a Microcontroller exclusively for USB control, which is ready for use. For use with a PC, simply install the **USB driver** and the **W20 Spirometry Software** in the PC. For both installations, consult the **W20 Spirometry Software User Manual**.

BLUETOOTH MODULE INSTALLATION

This case is similar to the above.
By inserting the optional Bluetooth module, the equipment is ready to transmit data via Bluetooth.
For use with a PC, simply install the **Bluetooth module** and the **W20 Spirometry Software** in the PC. The PC is then ready to receive the data transmitted by the equipment.
For both installations, consult the **W20 Spirometry Software User Manual**.

Once the Bluetooth module has been configured in the PC, a connection will be established every time the equipment and the PC are started.
Although the **DATOSPIR MICRO** internal Bluetooth module uses batteries, particularly during data transmission, it is wise to disable the module if no connection with the PC is required. This will extend the working life of the batteries.
The Bluetooth is enabled and disabled by accessing the Bluetooth option on the main screen.

EQUIPMENT PROTECTION

In compliance with the **Data Protection Act** (LOPD), the **DATOSPIR MICRO** has an equipment protection option accessed by PIN, accessed by a pin of 4 digits.
This option can be customised, enabled or disabled as required. Where enabled, a screen will appear requesting the PIN (user-configured) when the equipment is started.
If an erroneous PIN is entered three times, the equipment will lock and will switch off. On restarting it, a screen will appear requesting the unlock code or PUK (supplied to the purchaser of the equipment).

This prevents access to the equipment and, more specifically, to the private data it contains by unauthorised people.

For information on the **Data Protection Act** (LOPD), consult APPENDIX 2.

START-UP

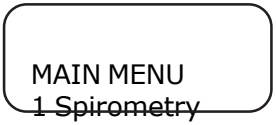
To start the **DATOSPIR MICRO** spirometer,

press the key .

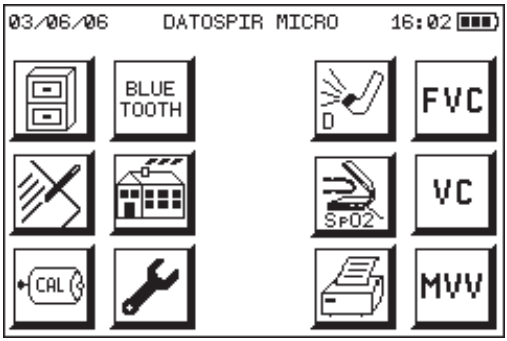
The equipment will then make a beeping sound and will check itself. The «**SIBELMED**» logo, the name of the equipment, the programme version and the address of SIBEL S.A. will appear on screen for two seconds.

If equipment protection is enabled, the PIN entry screen will appear.
If equipment protection is not enabled or if the correct PIN has been entered, the **MAIN MENU** will then be displayed, which varies according to the model.

Model A:



Models B and C:



NOTE:
The first time the equipment is started, the protection is disabled and the PIN is set to 0000. See Section 2.2 / 3.2 EQUIPMENT CUSTOMISATION to enable it and configure the PIN.

HANDLING THE EQUIPMENT

The spirometer has been developed to make it user-friendly, so that it is easy and simple to use. The equipment may seem difficult to handle, given its multiple functions, although its design and use will quickly show you that it is truly easy and intuitive for any medical staff.

All functions are accessible from the 4 silicon keys located underneath the screen (Model A) or using the icons on the screen that can be selected using a pointer (Models B and C).

All models can be connected as standard or optionally to an external printer, where this has been previously selected in the Customisation option. In this case, following the instructions of the corresponding printer.

1.6 OPERATING MODES

The **DATOSPIR MICRO** spirometer has two operating modes:

- HOME Mode
- HOSPITAL Mode

Each one is selected from the main screen.

HOME MODE

This operating mode means that the **DATOSPIR MICRO** can be programmed to control asthmatic patients at home.

See section **2.12 / 3.13 HOME MODE OPERATION**.

The equipment is very simple and easy to handle, presenting the measured value of PEF, FEV1 or FVC in a colour range of Green, Yellow and Red (semaphore), as programmed.
Spirometer operations by patients at home are saved in an internal database and subsequently transferred to the PC database for data analysis and storage.

HOSPITAL MODE

This option means that the **DATOSPIR MICRO** can be used as a sophisticated spirometer with the following functions:

- **Spirometry**
  . Patient Details (Reference, Age, Weight, Height, Sex, Index Smoker)
  . Atmospheric Conditions (Temperature, Pressure, Humidity)
  . Tests (FVC, VC, MVV , Bronchial Dilation)
  . Report

- **Customisation** (selectable options)
  . Spirometry (References/Parameters/Graphs/Diagnosis/ Dilation Modes/Warnings)
  . Home mode (Patient details / test data)
  . Printers
  . Standard curves (Retrieve standard / modify standard)
  . Battery
  . Language
  . Set clock (Time / Date)
  . Pulse oximetry

- **Calibration**

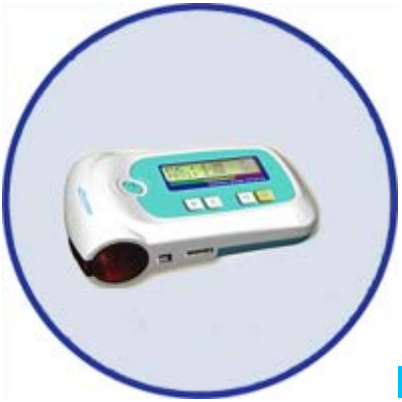
- Internal **Database** to save tests with alphanumeric and graphical data (depending on model).

- **Maintenance**
  . Warnings
  . LCD contrast
  . Equipment check
  . Equipment configuration
  . ATS curves

- **Function modes**
  . Home
  . Hospital

- **Pulse oximetry**

- **Bluetooth**



2. MODEL A OPERATION

All of the sections in this Chapter (except for 2.12 HOME MODE OPERATIONS) refer to **HOSPITAL MODE**.

2.1 FUNCTION TREE

The **DATOSPIR MICRO** spirometer function tree is shown for a better understanding of its structure. **This structure corresponds to Model A and is characterised by the fact that it contains text menus.**

The **DATOSPIR MICRO** Model A has 4 silicon keys located underneath the screen to move around the different menus in the equipment.

In general, the and keys enable you to move around the different menu options.

The key provides access to the selected option and the key takes you back to the previous menu.

The following can be accessed from the Main Menu, depending on the options included:

1. SPIROMETRY
2. CALIBRATION
3. DATABASE
4. CUSTOMISATION
5. MAINTENANCE
6. OPERATING MODE
7. BLUETOOTH

1.SPIROMETRY

1. FVC (Forced Vital Capacity Test)
   1. Start manoeuvre
   2. Results

3. Diagnosis
4. Save DB
5. Save PRE
6. Report
7. Delete
8. New patient

2. VC (Slow Vital Capacity Test)
   1. Start manoeuvre
   2. Results
   3. Save DB
   4. Save PRE
   5. Report
   6. Delete
   7. New patient

3. MVV (Maximum Voluntary Ventilation Test)
   1. Start manoeuvre
   2. Results
   3. Save DB
   4. Save PRE
   5. Report
   6. Delete
   7. New patient

4. Dilation (Post bronchial dilation test)
   1. PRE manoeuvres
      1. Start manoeuvre
   2. Results
   3. (Diagnosis)
   4. Save DB
   5. Report
   6. Delete
   2. Delete PRE

5. Total Report

6. New Patient

2. CALIBRATION

1. Calibration

2. DB calibration
    1. Register Data
    2. Delete Register
    3. Report

3. DATABASE

1. Search DB
    1. Results
    2. (Diagnosis)
    3. Report
    4. Delete test

2. Search patient
3. Search register
4. Summarised report
5. Delete DB

4. CUSTOMISATION

1. Spirometry
    1. References
        1. Adults
        2. Children
        3. Ethnic Factor
    2. Parameters
        1. FVC
        2. VC
        3. MVV
    3. Graphics
    4. Diagnosis
    5. Dilation modes
    6. Warnings

2. Home mode
    1. Patient details
    2. Test data
3. Printers

4. Standard
    1. Retrieve standard
    2. Modify standard

5. Battery
6. Language
7. Set clock
8. Pin

5. MAINTENANCE

1. Warnings
2. LCD contrast

3. Equipment check
    1. Printer
    2. CPU
    3. LCD
    4.Keypad
    5. ADCs
    6. Inputs

4. Equipment config.
    1. Reset
    2. Reindex
    3. Calibrate
    4. VC mode
    5. Update PIN

5. ATS curves
    1. FVC
    2. VC
    3. MVV

6. OPERATING MODE

1. Home mode
2. Hospital mode

7. BLUETOOTH

2.2 EQUIPMENT CUSTOMISATION

Every user should customise the **DATOSPIR MICRO** spirometer according to his requirements due to the multiple variety of options included.

The different options included in the Customisation menu are explained in detail in the previous section.

SPIROMETRY CUSTOMISATION

This option customises any suboptions specific to the spirometric tests

1. References
The type of reference required can be selected (SEPAR, ERS, KNUDSON, CRAPO, ZAPLETAL, MORRIS, AUSTRIA, GUTIERREZ-CHILI, CASTRO-BRAZIL, POLGAR-WENG, P. PADILLA-MEXICO, HANKINSON, A.J. CRUZ -MÉXICO, GOLSHAN-IRAN)) for adults and children and the ethnic factor.
It prioritises the age range selected for adults if a different table is chosen for children.
It extrapolates the values for the ages outside the table range selected.

2. Parameters
The observed or measured parameters to be used can be selected. This is only at display level or for the report. All the parameters are saved to the database and can be enabled at any time.

3. Graphics
The graphics can be saved to the database.

4. Diagnosis
The type of diagnosis can be selected (Miller or Snider, Kory & Lyons).

5. Dilation modes
The comparison mode can be selected in POST bronchial dilation.

6. Warnings
The printing of Non-conformity warnings regarding the operations with ATS/ERS criteria can be selected.

CUSTOMISATION OF THE HOME MODE

In this option it is possible to configure the **DATOSPIR MICRO** for use in home mode.

See Section **2.12 HOME MODE OPERATIONS**.

PRINTER CUSTOMISATION

In this option you can choose if you want to print in black and white or color. The Datospir Micro works only with HP-PCL printers.

To be able to print from the equipment you must:

1 Select the type of printer connected to the equipment (once this has been done you will not have to repeat this step unless the printer is changed).

2 Connect the equipment to the external printer using the Mini USB cable, code 305-600-040 (included, depending on model).

3 Switch the printer on.

STANDARD CONFIGURATION

This option memorises a user-defined customisation programme status to retrieve it at any time globally and automatically. This option restores the original customisation if it has been modified either voluntarily or by accident. In general, this configureation will correspond to that most often used.

1. Retrieve Standard
The configuration saved can be loaded as standard.

2. Modify Standard
The configuration to date can be saved for use as standard.

BATTERY CUSTOMISATION

The **DATOSPIR MICRO** works with two types of battery (alkaline or NiMh), independent to the battery selected in this section. This selection only affects the calculation made inside the equipment to indicate the battery levels.

LANGUAGE CUSTOMISATION

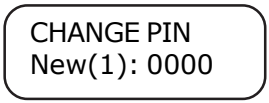
This option allows for the equipment language to be chosen.

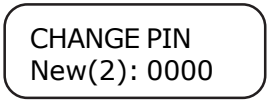
SET CLOCK

This option sets the time and the date of the clock inside the equipment.

EQUIPMENT PROTECTION CUSTOMISATION

This allows you to change the PIN required to start the equipment (if the protection option is enabled) and to enable or disable equipment protection.
The following screens will appear successively:



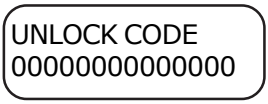


To enable protection, select YES on the Pin Enabled screen and enter the PIN in the New(1) and (2) screens.
To change the PIN, you must enter the current one. If an erroneous PIN is entered three times, the equipment will lock and will switch off.
See the following section (2.3 EQUIPMENT PROTECTION).

2.3 EQUIPMENT PROTECTION

If equipment protection has been enabled, the following screen will appear when it is started:

Enter PIN.
If the PIN configured in Equipment protection customisation is entered, access will be given to the **DATOSPIR MICRO** and the main screen will appear.
If an erroneous PIN is entered three times, the equipment will lock and will switch off. The following screen will appear when it is restarted:



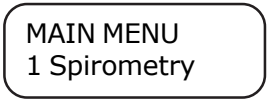
Enter the unlock code (PUK) supplied on purchasing the equipment.
If the correct code is entered, the **DATOSPIR MICRO** will unlock and the main screen will appear. From then on, the equipment will return to its initial status (Protection disabled and PIN 0000).
If an erroneous code is entered, the equipment will remain locked. This prevents access to the equipment and, more specifically, to the private data it contains by unauthorised people.

2.4 FORCED VITAL CAPACITY «FVC» TEST PROCEDURE

The procedures to be completed to carry out the **Forced Vital Capacity «FVC», slow Vital Capacity «VC» and Maximum Voluntary Ventilation «MVV»** tests are very similar. Therefore, only one detailed description will be given in this section.

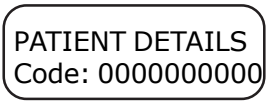
ENTERING PATIENT PARAMETERS

Start the **DATOSPIR MICRO** using the key and wait for the following screen to appear:



Press the key and the following will appear:

Press the key and the following will appear:



Enter the patient code (between 0 and 9999999999).

Select the digits using the keys or and or set the value for each digit.

Press the key to go to the next and so on in the remaining screens indicated.

PATIENT DETAILS Age (years): xx	Between 4 and 100
PATIENT DETAILS Height (cm): xxx	Between 50 and 230 cm
PATIENT DETAILS Weight (Kg): xx	Between 15 and 200 Kg
PATIENT DETAILS Sex: Man	Between male and female
PATIENT DETAILS I. Smoker: xx	Between 0 and 200 packs a day per number of years
PATIENT DETAILS Cig/day: xx	Between 0 and 20 cigarettes
PATIENT DETAILS Ethnic F.: xxx	Between 80 and 120%

The **Smoker Index** is the same as the number of cigarettes smoked a day divided by 20 and multiplied by the number of years smoking (cigarettes day x years smoking / 20).

The **ethnic factor** is used in areas without any parameters of reference that use some existing yet corrected in a certain percentage. This factor **MUST BE SET TO 100 IF NOT USED** and can only be modified through the Customisation Programme.

Press the key to go to the **FVC TEST** screen.

Use the or keys to select one of the following options:

FVC TEST
1 Start Manoeuvre

Allows for spirometric manoeuvres to be acquired

FVC TEST
2 Results

Displays the results of the best three manoeuvres

FVC TEST
3 Diagnosis

Displays the diagnosis according to the results obtained

FVC TEST
4 Save DB

Saves the selected manoeuvre to the Database

FVC TEST
5 Save PRE

Saves in the Database as PRE

FVC TEST
6 Report

Prints the report on any completed manoeuvre

FVC TEST
7 Delete

Deletes any manoeuvre

FVC TEST
8 New Patient

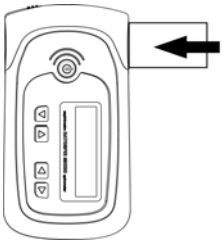
Option to change patient or to change some datails of an existing patient

ENTERING FORCED VITAL CAPACITY «FVC» TESTS

The technician to carry out the forced spirometry tests must know the normal procedures required so that the patient can be coached. Where this is not the case, certain documentation on the matter must be reviewed.

When undertaking spirometry, take the following steps into account:

1 Check that the turbine is correctly inserted with the mouthpiece, as in the figure.



2 Instruct the patient as to how to carry out the test, as his cooperation is vital for it to be completed correctly.

WARNING:
The test must be carried out by skilled staff. Review Chapter 7. SPIROMETRY TECHNIQUE or ask for a spirometry course from SIBEL S.A.

Patients can carry out the spirometry manoeuvres in two different ways:

- The first consists of starting to move the turbine with FORCED EXPIRATION followed by FORCED INSPIRATION, if required.

- The second consists of the patient breathing normally through the turbine and, when indicated by the technician, fill his lungs full of air and then start FORCED EXPIRATION followed by FORCED INSPIRATION, if required.

3 Inform the patient of the way of holding the equipment when using the spirometer, taking care not to press any key and fitting the nose clip as shown in the following figure.

4 Select the screen

FVC TEST
1 Start Manoeuv.

and press the

. key. The following screen will appear:

MEASURING

The equipment is held so that the doctor can see the screen while the patient is carrying out the tests.

On the left-hand side is a rectangle indicating that the equipmen is ready for the test to be started. The patient has **30 seconds** to begin. After this time if he has not started the equipment will switch to standby and must be pressed again.

After the expiratory manoeuvre, the second line of the screen will show a bar, movement of which is proportional to the volumen of the expiratory manoeuvre. The maximum value of the bar corresponds to a volume of **6 litres**.

At the end of the manoeuvre, one or more of the Warnings, if enabled in the Customisation Programme, may appear to warn that the manoeuvre is not compliant with ATS/ERS Criteria.
An indication is given to inform that the manoeuvre has not been carried out according to one of the following ATS/ERS criteria:

ET - Indicates that spiration has not completed satisfactorily, as the variation on volume in the last second of the manoeuvre was above 25 ml, or the manoeuvre has lasted less than 6 seconds (in patients aged over 10 and more) or less than 3 seconds (in patients aged 10 or less).

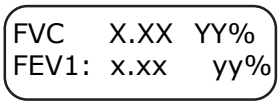
EX - Indicates that the start of expiration was not satisfactory, as the extrapolated volume is above 5% of the FVC or 0.15 litres. The ATS/ERS recommends it be less than 5% the FVC or 0.15 litres, whichever is highest.

The technician performing the spirometry may, where considered appropriate, disable these warnings in the Customisation Programme. In this case, they will also be removed from the printed report.

This disabling is only at display level. The warnings are still taken into account when ordering the manoeuvres.

5 Press the key, if the Warnings are enabled.

The following screen or similar will be shown, depending on the parameters selected in the Customisation Programme.



X.XX: Observed Value of the parameter, in this case FVC.
YY: % between the Observed value and the value of Reference.
x.xx: Observed Value of the parameter, in this case FEV1.
yy: % between the Observed value and the value of Reference.

ATTENTION: Check in the Customisation Programme that the REFERENCES and the ETHNIC FACTOR are suitably selected. The ethnic factor modifies the value of the References according to the percentage selected. 100% is equivalent to the unmodified standard value of the References.

Using the selection keys or it is possible to view the observed value and the percentage in relation to the value of reference for each customised parameter.
If a parameter does not have a Value of Reference, the corresponding percentage will not appear.

6 Press the key again and complete a new manoeuvre. As many manoeuvres as required can be completed. The **DATOSPIR MICRO** will always save the five best for FVC and VC and the three best for MVV, according to **ATS/ERS criteria (*)**.
No more than eight manoeuvres should be made so as not to tire the patient.

If three or more manoeuvres have been completed and the FVC and/or FEV1 parameters are flashing, this indicates that the repeatability criterion for one or both parameters has been met. This criterion indicates that the best two observed values of FVC and the best two of FEV1 differ in no more than 150 ml if the FVC is greater than 1 litre or in no more than 100 ml if the FVC is below or equal to one litre.

NOTE: Remember that the back key takes you back in the menu without losing the information available to date, except where you change patient.

(*) ATS/ERS criteria:
The manoeuvre with least warnings is considered the best (ET, EX). With the same number of warnings, the manoeuvre with the highest value sum of FVC+FEV1 is considered the best.

DISPLAYING RESULTS

The results can be seen once at least one manoeuvre has been completed. To do so, go back to the following screen

FVC TEST
1 Start Manoeuv.

and, using the △ or ▽ keys, select the option

FVC TEST
2 Results

Press the key and a similar screen to the following will appear:

RESULTS
M1 M2 [M3] M4 M5

Indicates the number of manoeuvres in the memory. The best (M1) will always be selected (flashing text) by default.

This screen indicates the following:

- Number of manoeuvres on memory. There may be from one to five manoeuvres.

- The manoeuvres are ordered according to **ATS / ERS criteria (*)** explained in the previous section, with M1 the best and M5 the worst.

- The manoeuvre between brackets [M3] indicates the position taken by the last manoeuvre entered.

- The flasing text indicates the manoeuvre selected.

To display the results, press .

To select another manoeuvre, press the keys or

Therefore, the brackets [ ] and the flashing text do not have to match.
On accessing the results of a test, the **best FVC** (**mFVC**) and the best **FEV1**(**mFEV1**) will appear first, followed by the results of the selected manoeuvre. The best FVC and FEV1 values may correspond to any of the available manoeuvres.

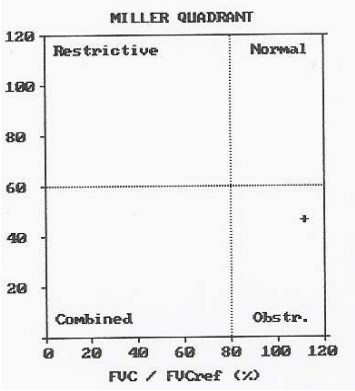
TYPE OF DIAGNOSIS

The **DATOSPIR MICRO** spirometer has two types of diagnosis that can be selected in the Customisation Programme.

NOTE:
If you do not agree with these two criteria, do not use them as a reference.
The diagnosis and the results of the test must always be validated by the specialist.

- **Miller Diagnosis**

This presents the following information: NORMAL, RESTRICTIVE, OBSTRUCTIVE or COMBINED, according to the criteria of the following chart



- **Snider, Kory & Lyons Diagnosis**

This is based on the following criteria:

If FVC > 80% of the FVC Reference
and FEV1 > 80% of the FEV1 Reference
Values in the range of reference. Normal Diagnosis

If FEV1/FVC% < FEV1/FVC% Reference
and FEV1 < 80% of the FEV1 Reference
Obstructive ventilatory disturbance

FEV1 < 80% Slight
FEV1 < 65% Moderate
FEV1 < 50% Intense
FEV1 < 35% Very Intense

If FEV1/FVC% < FEV1/FVC% Reference
and FVC < 80% of the FVC Reference
Non-obstructive ventilatory disturbance
FVC < 80% Slight
FVC < 65% Moderate
FVC < 50% Intense
FVC < 35% Very Intense

If FEV1/FVC% < FEV1/FVC% Reference
and FVC > 80% of the FVC Reference
Mixed ventilatory disturbance is suspected

If FEV1/FVC% < FEV1/FVC% Reference
and FEV1 > 80% of the FEV1 Reference
Mixed ventilatory disturbance is suspected

If the POST bronchial dilation test is carried out
and the FEV1 POST exceeds the base FEV1 or PRE by 15%
There is a positive response to the bronchial dilating drug

MEMORISING FVC TESTS

Memorising a test in the Internal Database

The **DATOSPIR MICRO** spirometer has an **Internal Database** that can save different tests to be subsequently transferred to a PC Database using **W20 Spirometry Software**.
This base may be of the **«L»** or **«H»**, depending on its capacity.

The process is similar to that described in the DISPLAYING RESULTS section, although previously selecting the option

FVC TEST
4 Save DB

Press the ▷ key and a similar screen to the following will appear, depending on the number of manoeuvres made:

SAVE DB
M1 M2 [M3] M4 M5

- The manoeuvres are ordered according to **ATS / ERS criteria (*)**, with M1 the best and M5 the worst.

- The manoeuvre between brackets [M3] indicates the position taken by the last manoeuvre entered.

- The flasing text indicates the manoeuvre selected (the best [M1] is selected by default)

Select the manoeuvre to be saved using the keys △ and ▽ (appearing between brackets) and press ▷.

The following screen will appear for a few seconds:

MANOEUVRE N.: X
SAVED

If you have made a mistake or wish to modify the manoeuvre, repeat the process.

(*) ATS/ERS criteria:
The manoeuvre with least warnings is considered the best (ET, EX). With the same number of warnings, the manoeuvre with the highest value sum of FVC+FEV1 is considered the best.

Memorising a test to compare it in POST bronchial dilation mode

This options allows for a test to be saved in PRE bronchial dilation mode to then compare it with POST bronchial dilation mode.

The process is similar to that described above, but previously selecting the option

FVC TEST
5 Save PRE

Press the ▷ key and a similar screen to the following will appear, depending on the number of manoeuvres made:

SAVE PRE
M1 M2 [M3] M4 M5

Select the manoeuvre to be saved using the keys △ and ▽ (appearing between brackets) and press ▷ .

The following screen will appear for a few seconds:

```
MANOEUVRE PRE
N.: X   SAVED
```

If you have made a mistake or wish to modify the manoeuvre, repeat the process.

PRINTING THE FVC

The **DATOSPIR MICRO** spirometer can print any manoeuvre made using an external printer.

The process is similar to that described in the previous section, but previously selecting the option

```
FVC TEST
6 Report
```

Press the key and a similar screen to the following will appear:

```
REPORT
[M1] M2
```

Check that the printer is ready and connected. Select

the manoeuvre to print (flashng text) and press . **The best (M1) is recommended.**

The printer will present a report similar to the following:

Sibelmed®

DATOSPIR MICRO SIBEL S.A.
ROSSELLO 500 08026 BARCELONA

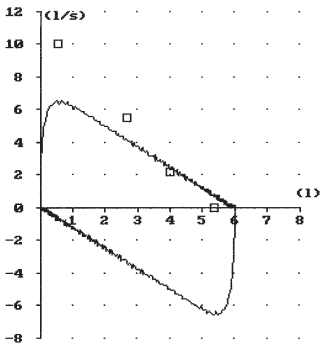
PULMONARY FUNCTION TEST **DATOSPIR MICRO**

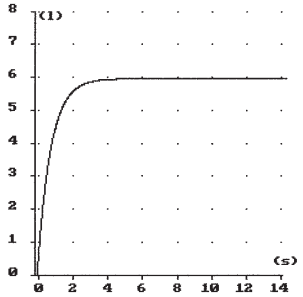
Code: 0000000001 Date: 04/06/2006 Time: 11:34
Name:
Sex: Male Age(y): 27 Height(cm): 174 Wt.(Kg): 68
Temp(°C): 26 Pres(mmHg):760 Humidity(%): 60 Smok. I.: 0
References: SEPAR Ethnic F.(%):100
Reason:
Origin:
Technician:
Bios Ver.: 5115AB-1.00 Prog Ver.: 5115AF-1.00

FVC REPORT **MANOEUVRE No.: 1/1**

PARAMETER		OBS	REF	(%)
Best FVC	(l)	5.99	5.35	112
Best FEV1	(l)	4.26	4.27	100
FVC	(l)	5.99	5.35	112
FEV1	(l)	4.26	4.27	100
FEV1/FVC	(%)	71.17	80.44	88
PEF	(l/s)	6.50	10.11	64
MEF50%	(l/s)	3.78	5.52	68
FEF25%-75%	(l/s)	3.42	4.50	76
FEV1/FEV0.5		1.55	1.45	107
FEV1/PEF	(%)	10.93	6.64	165

Comments: .....
.....





This will include the parameters and graphs corresponding to the selected curve.
If you do not want graphs, certain parameters, the diagnosis and/or ATS/ERS warnings to appear, disable them as described in Section 2.2. EQUIPMENT CUSTOMISATION.

WARNING
REMEMBER THAT THE BEST MANOEUVRE CORRESPONDS TO THE ONE SAVED IN POSITION «M1» AND WILL BE SELECTED BY DEFAULT.

If you want a global printout of the report, including the FVC, VC and MVV tests made on a patient, follow the steps described in the General Report Printing Section.

The following screen will appear during the printing process:

The top line indicates the percentage of the report produced.

Printing can be cancelled at any time by pressing the key .

DELETING A MANOEUVRE MADE

The **DATOSPIR MICRO** spirometer deletes any manoeuvre made, whether it is because you are doubtful as to whether its values are correct due to a defective performance, which may distort the results, or because of any other reason.

The process is similar to that described in the previous section, but previously selecting the option:

FVC TEST
7 Delete

Press the ▷ key and a similar screen to the following will appear:

DELETE
[M1] M2

Select the manoeuvre to delete (flashing) and press ▷

The following screen will appear:

WANT TO DELETE
THE MANOEUVRE?

Press the ◁ key to cancel and not delete the manoeuvre.

If you press the ▷ key to delete the manoeuvre, the following screen will appear:

MANOEUVRE N.: X
DELETED

OTHER TESTS ON THE SAME PATIENT

You can do the following after carrying out the FVC test on a patient:

- A **VC** on the same patient
- An **MVV** test on the same patient
- A **Post bronchial dilation** test on the same patient
- Print the **general report** of all tests on the same patient
- Start the test process on **another patient**.

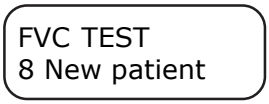
The spirometer saves the best manoeuvre of each FVC, VC, MVV and/or Bronchial dilation test to print a general report, where required, containig them all before going on to another patient.

From the next screen and using keys or

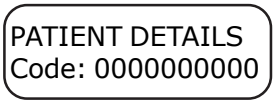
select any of the first four options.

CHANGE PATIENT

This option is used to enter a new patient or to change some details of an existing patient.
The process is similar to that described in the previous section, but previously selecting the option:



Press the key and the following screen will appear:



Enter the patient code required (between 0000000000 and 9999999999).

If you wish to modify some details of an existing, enter his code.

Follow the procedure designed in the **ENTERING PATIENT PARAMETERS** procedure to enter the details of a new patient or to modify the details of an existing patient.

If you have not saved the tests completed to date, the following warning will appear after the last screen of data:

If you press , the tests completed will be saved in the database.

If you press , the tests completed will not be saved in the database and **CANNOT BE RECOVERED**.

All the tests completed will then belong to the new patient.

NOTE:
In the event of having modified some details of an existing patient, his parameters will be recalculated taking the changes made into account.

2.5 SLOW VITAL CAPACITY «VC» TEST PROCEDURE

The procedure to carry out the slow Vital Capacity «VC» test is similar to that described in Section **2.4 FORCED VITAL CAPACITY «FVC» PROCEDURE** with the following variations:

1 If the test is carried out on the same patient, as described in the **OTHER TESTS ON THE SAME PATIENT** section,

go back using the ◁ key to the Test Selection window and select, using keys △ or ▽ , the **VC** test.

SPIROMETRY
2 VC

If the patient is new, begin as described in the **ENTERING PATIENT PARAMETERS** section.

2 Instruct the patient as to how to carry out this type of test, as his cooperation is vital for it to be completed correctly.

3 The maximum time allowed for the manoeuvre is **45 seconds**. The equipment saves a maximum of **five manoeuvres**, ordered according to the VC value, where M1 is the best VC and M3 the worst.

4 To measure the ERV and TV parameters correctly, each manoeuvre must have at least four respiratory cycles.

5 The register of parameters and graphics is as shown below.

Sibelmed®

DATOSPIR MICRO SIBEL S.A.
ROSSELLO 500 08026 BARCELONA

PULMONARY FUNCTION TEST

DATOSPIR MICRO

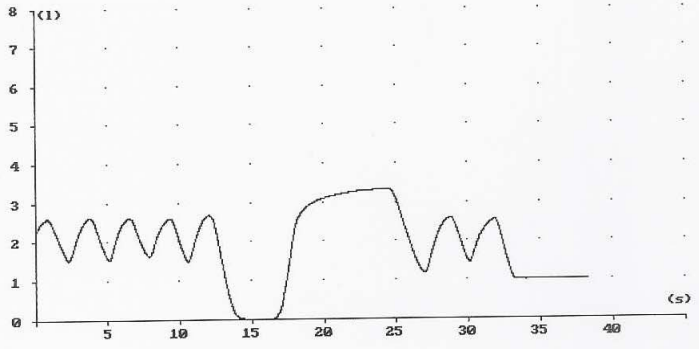
Code: 0000000001
Name:
Sex: Male
Temp(°C): 26
References: SEPAR
Reason:
Origin:
Technician:
Bios Ver.: 5115AB-1.00

Date: 03/22/2006 Time: 17:52
Age(y): 26
Pres(mmHg): 760
Height(cm): 174 Wt.(Kg): 68
Humidity(%): 60 Smok. I.: 0
Ethnic F.(%): 100
Prog Ver.: 5115AF-1.00

VC REPORT MANOEUVRE No.: 1/1

PARAMETER		OBS	REF	(%)
VC	(1)	3.36		
TV	(1)	1.11		
ERV	(1)	0.72		

Comments: .....
.....



2.6 MAXIMUM VOLUNTARY VENTILATION «MVV» TEST PROCEDURE

The procedure to carry out the Maximum Voluntary Ventilation «MVV» test is similar to that described in Section **2.4 FORCED VITAL CAPACITY «FVC» PROCEDURE** with the following variations:

1 If the test is carried out on the same patient, as described in the **OTHER TESTS ON THE SAME PATIENT** section,

go back using the ◁ key to the Test Selection window and select, using keys △ or ▽ , the **MVV** test.

SPIROMETRY
3 MVV

If the patient is new, begin as described in the **ENTERING PATIENT PARAMETERS** section.

2 Instruct the patient as to how to carry out this type of test, as his cooperation is vital for it to be completed correctly.

3 The maximum time allowed for the manoeuvre is **15 seconds**. The equipment saves a maximum of **three manoeuvres**, ordered according to the MVV value, where M1 is the best MVV and M3 the worst.

4 The register of parameters and graphics is as shown below.

Sibelmed®

DATOSPIR MICRO SIBEL S.A.
ROSSELLO 500 08026 BARCELONA

PULMONARY FUNCTION TEST **DATOSPIR MICRO**

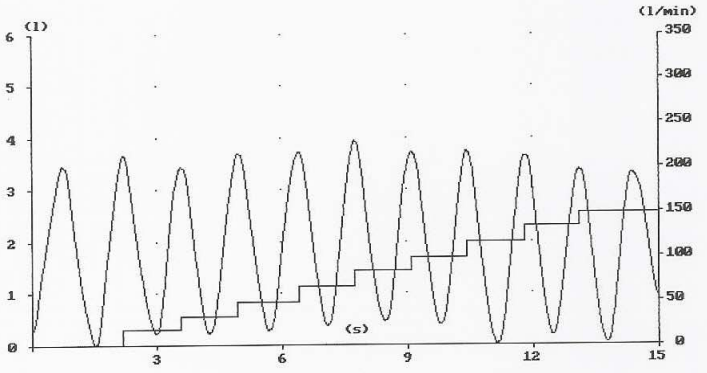
Code: 0000000001 Date: 03/22/2006 Time: 17:52
Name:
Sex: Male Age(y): 26 Height(cm): 174 Wt.(Kg): 68
Temp(°C): 26 Pres(mmHg):760 Humidity(%): 60 Smok. I.: 0
References: SEPAR Ethnic F.(%):100
Reason:
Origin:
Technician:
Bios Ver.: 5115AB-1.00 Prog Ver.: 5115AF-1.00

MVV REPORT **MANOEUVRE No.: 1/1**

PARAMETER		OBS	REF	(%)
MVV	(l/min)	150.82	179.00	84
Br / min		44.12		

Comments: .....

.....



2.7 POST BRONCHIAL DILATOR SPIROMETRY PROCEDURE

The **DATOSPIR MICRO** spirometer allows for Post bronchial dilation tests to be carried out in FVC, VC and MVV provided a test has previously be completed in PRE bronchial dilator mode and saved to the database.

The purpose of this operating mode is to provide PRE and POST spirometric results of applying a bronchial dilating drug in the same report.

The procedure to carry out Post bronchial dilating Spirometry is as follows:

1 Complete a FVC, VC or MVV test on the patient before applying the dilating drug, as described in the previous sections.

2 Memorise the PRE test in the database to compare it in POST mode, as explained in MEMORISING FVC TESTS in Section 2.4.

3 Apply the dosage of bronchial dilating drug established by the specialist to the patient and wait for the standardised period.

4 Go back using the ◁ key to the Test Selection window and select, using keys △ or ▽ ,

SPIROMETRY
4 Dilation

Select the screen:

DILATION
1 PRE manoeuvres

and press .

The tests memorised in PRE mode will then be displayed.

5 Select the PRE test with which it is to be compared and press .

6 The proceed as indicated in Section **2.4 FVC TEST PROCEDURE**.

The only variation is in point 5, as the % is weighted in relation to the observed values in Pre bronchial and Post bronchial mode.

If the printed report is requested, the data is presented as shown below. Three columns of data can be seen:

- PRE (PRE bronchial dilator Observed Values)
- POST (POST bronchial dilator Observed Values)
- %WGT (% weighted between the POST and PRE values)

%WGT = 100 x 2 (POST-PRE) / (POST+PRE)

(See J.E. Cotes: Lung Function. Assessment and Aplication in Medicine. Blackwell Sci. 4th Edition 1979, p52-53)

Sibelmed®

DATOSPIR MICRO SIBEL S.A.
ROSSELLO 500 08026 BARCELONA

PULMONARY FUNCTION TEST **DATOSPIR MICRO**

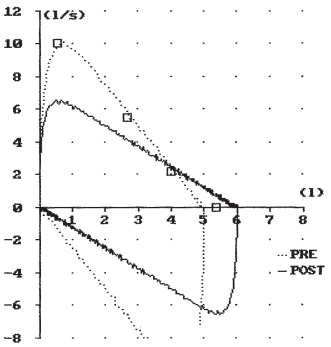
Code: 0000000001 Date: 04/06/2006 Time: 11:34
Name:
Sex: Male Age(y): 27 Height(cm): 174 Wt.(Kg): 68
Temp(°C): 26 Pres(mmHg):760 Humidity(%): 60 Smok. I.: 0
References: SEPAR Ethnic F.(%):100
Reason:
Origin:
Technician:
Bios Ver.: 5115AB-1.00 Prog Ver.: 5115AF-1.00

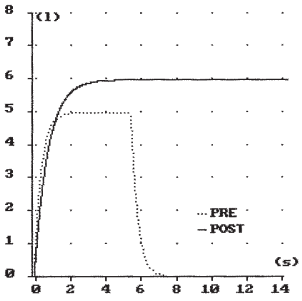
FVC REPORT **MANOEUVRE No.: 1/1**

PARAMETER		PRE	REF	(%)	POST	%P
Best FVC	(l)	5.00	5.35	93	5.99	18
Best FEV1	(l)	4.57	4.27	107	4.26	-6
FVC	(l)	5.00	5.35	93	5.99	18
FEV1	(l)	4.57	4.27	107	4.26	-6
FEV1/FVC	(%)	91.57	80.44	114	71.17	-24
PEF	(l/s)	9.87	10.11	98	6.50	-40
MEF50%	(l/s)	6.16	5.52	112	3.78	-47
FEF25%-75%	(l/s)	5.69	4.50	126	3.42	-49
FEV1/FEV0.5		1.30	1.45	90	1.55	17
FEV1/PEF	(%)	7.72	6.64	116	10.93	34

Comments: .....

.....





2.8 CALIBRATION PROCEDURE

GENERAL OBSERVATIONS

The Normative in force regarding spirometry recommends that all spirometers be perfectly calibrated. This is due to the alterations that may modify the characteristics of the electronic circuits and mechanical aprts over time and cause a change in the spirometer calibration factors. Hence, a calibation system has been incorporated based on a volume signal of reference (e.g. a syringe).

Furthermore, this calibration factor must take the changes in volume associated to atmospheric conditions into account. The most influential factor is temperature.

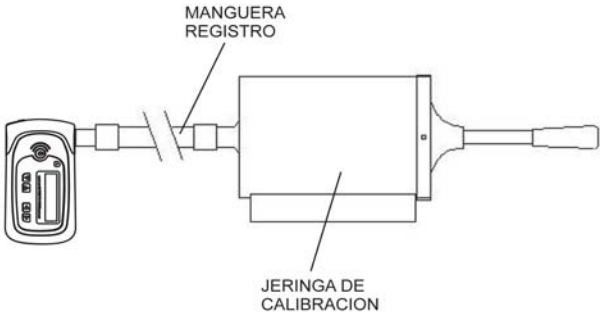
The **DATOSPIR MICRO** includes a Calibration Programme for fast (less than one minute) and easy checking and auto-correcting of diversion in the measurements taken based on a standard or reference volume for the quality control of the different spirometric tests.

The regularity of calibration depends on the user, although normative recommends it be done on a daily or weekly basis.

CALIBRATION PROCESS

The calibration process is as follows:

1 Install the spirometer and the syringe as in the figure



2 Start the **DATOSPIR MICRO** using the key and wait for the following screen to appear:

MAIN MENU
1 Spirometry

3 With the keys or select:

MAIN MENU
2 Calibration

4 Press , the following screen will appear:

CALIBRATION
1 Calibration

5 Press and enter the volume of the syringe in litres (between 0 and 6 litres, depending on the syringe)

CAL. DATA
Volume (l): x

If a 0 is entered, the default factors are used (Fct = 1 and NPulses = 188) and the calibration process is completed.

NOTE:
Where no syringe is available, the value entered in Volume is not relevant and is not taken into account when automatically calibrating the equipment.

6 Press . The following screen will appear:

CAL. DATA
No. Pulses: xxx

If the number of pulses associated to its turbine is as appears on screen, continue without modifying it.
If it is different, enter the number of turbine pulses. In this case, press and the following message will appear:

Confirm change
in N.Pulses?

Press and the factors will be calculated and the calibration process will conclude.

In case of pressing the number of pulses will not change and will return to the previous screen.

NOTE:
Each turbine is factory calibrated individually and is associated to a factor equivalent to the pulses / litre detected and printed on it. Although dispersion among turbines is within ±3%, it is worth entering this factor in the spirometer if the turbine is changed to obtain the maximum measurement precision.

Where no syringe is available, it is very important to enter the No. of Pulses of the turbine so that the equipment can be automatically calibrated.

7 Press . The atmospheric temperature (ºC) detected will appear thanks to a sensor inside the equipment. This can be modified if required.

CAL. DATA
Temp (ºC): xx

8 Press . The relative humidity (%) entered in the last calibration will appear. This can be modified if required.

CAL. DATA
Humidity (%): xx

9 Press . The atmospheric pressure (mmHg) entered in the last calibration will appear. This can be modified if required.

CAL. DATA
Pres(mmHg): xxx

10 Press , the following screen will appear:

CALIBRATION
Start Calibra.

11 Press again and start emptying the syringe for **two or more consecutive cycles** (one cycle is equal to emptying and filling the syringe). When emptying and filling the syringe piston must move all the volume used as a reference. If this is not done correctly, the equipment will detect it as «incorrect manoeuvres».
Furthermore, this process should be completed in a regular and uniform manner, without causing flow rates that are too high or too low. Where this is not the case, you will be told to repeat the manoeuvre.
The time of each cycle (emptying plus filling the syringe) most be no less than four seconds and no more than ten.
The equipment waits for 30 seconds for calibration to begin. The process must be restarted if this time is exceeded.

During calibration, the second line of the screen will show a bar, movement of which is proportional to the volumen applied.
On completion, the following screen or similar will appear if the process was correct:

CALIBRATED! Ve = Vi = 3.00 l < 2%	Calibrated volumes

12 Once the **DATOSPIR MICRO** has been calibrated, press

and the screen will return to the Start Calibration option

CALIBRATION REGISTER

The spirometer has a register containing the expiratory and inspiratory factors of the **last ten calibrations** performed. This is extremely useful for centres requiring a quality control of the processes they use.

To access this register, select the option:

CALIBRATION 2 Calibration DB

Press and using keys and access the option required:

CALIBRATION DB 1 Reg. Data

Displays the data on the last ten calibrations

CALIBRATION DB
2 Delete Reg.

Deletes the data on the calibrations saved

CALIBRATION DB
3 Report

Prints the register with the calibrations

2.9 INTERNAL DATABASE

The **DATOSPIR MICRO** has an Internal Database as standard that saves the different tests made using the equipment and subsequently displays them, prints them and/or transfers them to a PC or other computerised system for storage or management.

The base information remains, even when the equipment is turned off or the batteries are removed.

There are two bases with the same functions but different capacities:

Database «L»
Database «H»

The tests that can be saved (using a six-second FVC as reference) are:

Database «L» 150
Database «H» >1000

The saving of the tests has already been described in the sections corresponding to each test.

The database always saves all the spirometric parameters of each of the different test modalities, FVC, VC, MVV or Dilation, despite them not being selected in the Customisation programme.

Different functions are possible from the spirometer:

1 Search the database
2 Search for a patient

3 Search for a register
4 Print a summarised report
5 Delete the database

To do so, start the **DATOSPIR MICRO** using the key and wait for the following screen to appear:

MAIN MENU
1 Spirometry

Using the or keys, select the option:

MAIN MENU
3 Database

Press the key and with or select the required function.

DATABASE SEARCH

The **DATOSPIR MICRO** displays the parameters saved in the database for each test. If this is to be carried out on a regular basis, use the **W20 Spirometry Software** to conveniently view all the saved parameters.

Select the option:

DATABASE
1 Search DB

to display the results of the tests saved in the database, consult the diagnosis of each one (if the option is enabled), print a report or delete a test from the database.

Press the key ▷ and with △ or ▽ select the option required:

Pat. Code Test
1 Results

Pat. Code Test
2 Diagnosis

Pat. Code Test
3 Report

Pat. Code Test
4 Delete test

PATIENT SEARCH

Select the option:

DATABASE
2 Search Pat.

to search for a patient in the database.

Press the key and enter the patient code.

REGISTER SEARCH

Select the option:

DATABASE
3 Search Reg.

to search for a register in the database.

Press the key and enter the register number.

SUMMARISED REPORT

Select the option:

DATABASE
4 Summ. Report

to print a report with the list of tests saved in

the database. Press the key .

DELETE DATABASE

Select the option:

DATABASE
5 Delete DB

to delete the entire database Press the key .

2.10 MAINTENANCE PROGRAMME

The equipment has a maintenance programme to adjust and/or check the working order of certain options.

From the Main screen, press keys or to choose:

MAIN MENU
5 Maintenance

Press the key to access the Maintenance options.

Using keys and , you can move around the different options to:

1 Configure the calibration and/or maintenance warnings
2 Adjust the screen contrast
3 Auto-check the equipment
4 Configure the equipment
5 Check with pre-saved standard curves

WARNINGS

Select the option:

MAINTENANCE
1 Select Warning

This option indicates the tests completed and allows for the periods in days between calibrations or between preventative maintenance work on the equipment to be defined.
If the days specified without calibration or maintenance are exceeded, the equipment warns of such by displaying a sign every time it is started. If 0 days is entered, a warning is never given.

Press and the next screen will appear to enter the calibration period.

Calibration Period: x

Press and the next screen will appear to enter the maintenance period.

Maintenance Period: xxx

Press and an informative screen will appear with the date of the last maintenance work.

Press and an informative screen will appear with the total number of tests completed.

Press and an informative screen will appear with the number of tests completed since the last maintenance work.

LCD CONTRAST

Select the option:

```
MAINTENANCE
2 LCD contrast
```

Using keys and , this option enables you to configure the screen contrast.

EQUIPMENT CHECK

Select the option:

```
MAINTENANCE
3 Equip. Check
```

This option allows for different parts of the equipment to be checked.

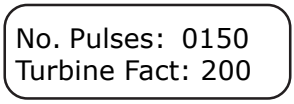
Using keys and select:

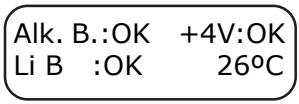
```
EQUIPMENT CHECK
1 Ext. Printer
```

to check the external printer selected. The SIBELMED logo will be printed along with the heading lines and 10 lines of characters.

```
EQUIPMENT CHECK
2 ADCs
```

to see the values of the following variables:





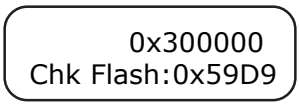
to test the LCD using a:

- Bar test: a bar is drawn alternately on the top and bottom line of the LCD.

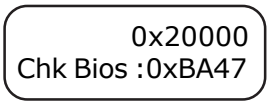
- Contrast scan

to check the CPU:

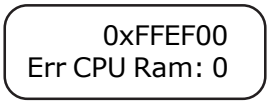
1 Calculates the flash checksum. The top line indicates the current direction and the bottom line the checksum.



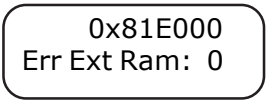
2 Calculates the bios checksum.



3 Tests the internal RAM: successively writing and reading the value 0x55 in the internal RAM. The top line indicates the current direction and the bottom line the number of errors in the write/read process.



4 Tests the external RAM: the same process as for the internal RAM.



to check that the automatic on and off of the equipment works properly. On selecting this option, the equipment switches off and on automatically after 5 seconds.

EQUIPMENT CONFIGURATION

Select the option:

MAINTENANCE
4 Config. Equip.

This option allows for different options of the equipment to be configured.

Using keys △ and ▽ select:

CONFIG. EQUIP.
1 Reset

to reset all equipment variables.

CONFIG. EQUIP.
2 Reindex

to reindex the database.

CONFIG. EQUIP.
3 Calibration

to enter the turbine pulses.

CONFIG. EQUIP.
4 VC mode

to choose the presentation mode for the VC curve (Normal : expiration upwards / Inverted: expiration downwards).

CONFIG. EQUIP.
5 Update Key

to consult the updating key for the programme in Flash.

ATS CURVES

Select the option:

MAINTENANCE
5 Standard Curves

This option checks the correct working order of the equipment using pre-saved curves.

Using keys △ and ▽ select:

STANDARD CURVES
1 FVC

STANDARD CURVES
2 VC

STANDARD CURVES
3 MVV

Select the option and following the instructions on the screen, which are similar to the FVC, VC and MVV procedures. With these curves you can operate the equipment as if they were real patient curves, with slight exceptions.

2.11 UPDATING INTERNAL SOFTWARE

The **DATOSPIR MICRO** spirometer has two types of internal software:

- Bios (basic hardware control programme)
- Flash (programme containing all the equipment options)

The update option allows for the version of Bios and/or Flash to be updated without having to take the equipment to the factory and without having to open it.

WARNING
Both updates are completed through the series port (RS232)

BIOS UPDATE

The updating process for the BIOS programme is as follows:

1 Run the **W-20 Spirometry Software** and access the Configuration - Hardware Test option.
Run a communications test to check that the connections are correct.

2 Switch the equipment off.

3 With the **DATOSPIR MICRO** switched off, remove the rear cover, disconnect the bluetooth (where applicable) and turn both switches ON.

WARNING
This option should be carried out by an expert or specialist.

4 Turn the equipment and support it on the table with the screen visible.

5 Press the key for 1 second and release. Nothing will appear on the screen.

6 Copy the Bios file (DMBios.tsk) into the **\FIRMWARE** directory of the application (W20).

7 Run the **W-20 Spirometry Software**, access the Configuration - Links option and check that the **DATOSPIR MICRO** is selected.

8 Access the Configuration - Utilities - Update Bios option.

9 Follow the instructions on screen and wait for the process to end.

10 Once completed, turn both updating switches OFF again, replace the Bluetooth (where applicable) and close the cover.

FLASH UPDATE

Flash can be updated for a new version of the programme (in which improvements have been included) or to add another option to the equipment (dilation option, bluetooth, etc.).
In the case of the latter, SIBEL, S.A. will provide a new update key.

In case of the former, consult the key in the equipment before starting the update process:

Switch the **DATOSPIR MICRO** on and select the following from the main menu

MAIN MENU
5 Maintenance

Access the option

MAINTENANCE
4 Config. Equip.

and consult the update key in

CONFIG. EQUIP.
5 Update Key

Stop the DATOSPIR MICRO.

The updating process is as follows:

1 Run the **W-20 Spirometry Software** and access the Configuration - Hardware Test option.
Run a communications test to check that the connections are correct.

2 Switch off the **DATOSPIR MICRO**.

3 Start the **DATOSPIR MICRO** while keeping the

key pressed down. This will run the

programme in BIOS to update FLASH.

4 The BIOS **access key** is then requested

(Press and then) to prevent any user from being able to access by mistake.

5 Copy the new file provided by SIBEL containing the update (DMFlash.tsk) to the **\FIRMWARE** directory of the application (W20).

6 Run the **W-20 Spirometry Software**, access the Configuration - Links option and check that the **DATOSPIR MICRO** is selected.

7 Access the Configuration - Utilities - Update Flash option (the **W-20 Spirometry Software** in «demo» mode provided on purchasing the equipment is enough).
A dialogue box will open where the **update key** (that previously consulted if this is a version update or that provided by SIBEL if it is an option update) must be entered.

8 The new programme will be transmitted. The process may take around **10 minutes**, depending on the PC.

9 Switch off the **DATOSPIR MICRO**.

2.12 HOME MODE OPERATIONS

The **DATOSPIR MICRO** spirometer is very useful to monitor and control asthmatic patients or others to suit the specialist's criteria, whether they are at home or in hospital.
In this option, the spirometer is extremely user-friendly equipment, as the sequence of instructions on the screen will guide patients during spirometric manoeuvres. In turn, it automatically saves the best manoeuvres made in the different tests to memory. This enables the specialist to subsequently analyse them and make the corresponding diagnosis.
It is also possible to transfer them from the equipment Database to the PC Database using **W20 Spirometry Software**.

Three stages can be described for a better understanding of this operating mode:

1 Spirometer configuration
2 Acquisition of spirometric tests
3 Displaying of the information saved

CONFIGURATION

The specialist must configure the spirometer in HOME mode and provide the patient with the necessary instructions. The process to follow is as described below:

Start the **DATOSPIR MICRO** using the

key and wait for the following screen to appear:

MAIN MENU
1 Spirometry

Using the or keys, select the option:

MAIN MENU
4 Customise

and then

CUSTOMISATION
2 Home Mode

Home mode customisation includes the customisation of the patient's details and the test data.

Select:

HOME MODE
1 Patient Details

and enter the data requested on the successive screens

PATIENT DETAILS Code: xxxxxxxxxx	Between 0 and 9999999999
PATIENT DETAILS Age (years): xx	Between 4 and 100
PATIENT DETAILS Height (cm): xx	Between 50 and 230 cm
PATIENT DETAILS Weight (Kg): xx	Between 15 and 200 Kg

PATIENT DETAILS Sex: Female	Between male and female
PATIENT DETAILS Cig/day: xx	Between 0 and 20 cigarettes

Select

HOME MODE
2 Test data

to configure the semaphore and the alarms. The following screen will appear:

SEL. SEMAPHORE
[FVC] FEV1 PEF

Select the parameter of reference for the manoeuvres.

The value of **REFERENCE** will then appear, depending on the age, weight, etc. of the patient and the tables enabled in the Customisation programme. This value can be changed by the specialist for patients who, under controlled conditions of asthma, have a significant deviation regarding the standard of the reference. The value programmed will be equivalent to **100%** in the subsequent control.

REFERENCE VALUE
FVC: xx.xx

Select the value, where necessary, and press .

The levels must be defined in percentages in relation to the value previously selected from among the different semaphore indicators. The standard levels are:

GREEN Zone	Between 100% and 80%	**Normal**
YELLOW Zone	Between 80% and 50%	**Precaution**
RED Zone	Between 50% and 0%	**Warning**

SEMAPHORE LEVELS
Min: xxx Max: xxx

Select the level, where necessary, and press .

The alarms are a reminder for the patient, as the test can be taken at any time, despite it being different to the time programmed, and the time it is taken is recorded.

DAILY TESTS
No. of Tests: x

None, one, two or three daily alarms for the test

TEST 1
xx : xx : xx

Time of the 1st test

TEST 2
xx : xx : xx

Time of the 2nd test

TEST 3
xx : xx : xx

Time of the 3rd test

TEST DAYS MoTuWeThuFrSaSu	Days of the week when the tests are taken

Home mode is now configured so that you simply have to access the following option from the main screen to activate it:

MAIN MENU 6 Hospital mode	Shows the current mode

Press the key to change mode and switch the equipment off.

ACQUISITION OF SPIROMETRIC TESTS

Once the equipment has been configured by the specialist the test acquisition process can begin.

The storage capacity is 150 or 1000 tests, depending on the database ('L' or 'H').

The specialist will explain the test to the patient, particularly the forced expiration manoeuvre process, the equipment operating sequence and when the tests should be taken.

The operating sequence is as follows:

- If **start-up** is **manual** (the patient starts the equipment):

1 The start screen will appear along with the model, the programme version and the bios version (programme run during booting), the date and the time.

• If **start-up** is **automatic** (because it is the time programmed in Alarms):

1 The equipment will start up and the start screen will appear along with the model, the programme version and the bios version, the date and the time.
The following screen will then appear:

START THE TEST
PRESS THE KEY

and the equipment will issue a **beeping** sound **every 10 seconds**.

If, for **2 minutes**, is not pressed, the equipment will switch off.

Press the key .

2 The following screen will appear:

BLOW

The patient is given **30 seconds** to start the FORCED EXPIRATION manoeuvre.

3 The following screen is then displayed:

BLOW AGAIN

4 The patient has to perform three expiratory manoeuvres. After the three manoeuvres, an arrow will appear to indicate the semaphore zone in question (GREEN, YELLOW or RED), in line with the programme produced by the specialist.

The equipment automatically saves the best manoeuvre to memory, according to the following criteria:

- The one with the best sum of FVC + FEV1 is considered the best.
- The one with the best FVC is considered the best.
- The one with the best FEV1 is considered the best.
- The curves with warnings (ET, EX) are considered the worst.

5 As a guideline for subsequent control and diagnosis, patients can note down, where applicable, one or several of the different symptoms during the test (COUGH, PANTING, BREATHING DIFFICULTIES or MUCOSITY).

The severity can be chosen for each symptom from among the following values:

- NONE (No symptom)
- LOW
- MEDIUM
- HIGH

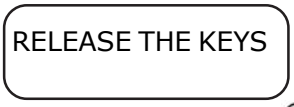
IMPORTANT NOTE:

Proceed as follows to go from HOME MODE to HOSPITAL MODE:

For equipment with the key **.**

Keep the keys **and** **pressed down at the same time and restart by pressing** **.**

The following warning will appear on screen after a few seconds:



You should then release keys **and** **.**

The spirometer is now in HOSPITAL mode.

DISPLAYING SAVED INFORMATION

The information saved can be displayed on the **DATOSPIRMICRO** spirometer or on the PC using the **W20 Spirometry Software**. In both cases, the aforementioned options can be chosen (consulting parameter, printing a report, etc.).

3. MODELS B AND C OPERATION

All of the sections in this Chapter (except for 3.13 HOME MODE OPERATION) refer to **HOSPITAL MODE**.

3.1 FUNCTION TREE

The **DATOSPIR MICRO** spirometer function tree is shown to enable a better understanding of its structure. **This structure corresponds to Models B and C and is characterised by the fact that it contains graphic menus.**

To move around the different equipment menus, DATOSPIR MICRO Models B and C have a pointer to select the icons appearing on screen.
The character (number or letter) must also be selected to write in the numeric or alphanumeric fields using the pointer.

WARNING
It is recommendable to use the pointer included with DATOSPIR MICRO. SIBEL S.A. is not responsible for any damage caused where other pointers are used.
Pointed objects must not be used under any circumstances.

The following can be accessed from the Main Menu, depending on the options included:

SPIROMETRY
CALIBRATION
DATABASE
CUSTOMISATION
MAINTENANCE
OPERATING MODE
PULSE OXIMETRY
DILATION
REPORT
BLUETOOTH

SPIROMETRY

- Forced Vital Capacity «FVC» Test
  - Test data
    - Patient
      - Code
      - Full name
      - Age, height, weight and sex
      - Smoker index
      - Ethnic factor
    - Atmosphere
      - Temperature
  - Start of the spirometric manoeuvre
  - Graph presentation
    - Flow/Volume (only in FVC)
    - Volume/Time
  - Manoeuvre selection
  - Select the best manoeuvre
  - Manoeuvre data selected
    - Memory for five manoeuvres
    - Deleting a manoeuvre
    - Diagnosis
    - Saving test for Post bronchial dilation
    - Saving test on the Database
  - Test printout
- Slow Vital Capacity «VC» Test
  - Similar to the FVC
- Maximum Voluntary Ventilation «MVV» Test
  - Similar to the FVC

CALIBRATION

- Calibration using a syringe
- Report on the latest calibrations

DATABASE

- Search by patient code or register number
- Summarised display of the tests saved
- Printing and displaying a test

- Deleting a test
- Summarised printing of the tests saved

CUSTOMISATION

- Standard Configuration
  - Retrieving the configuration
  - Saving the configuration
- Home mode customisation
  - Patient and test data
- Database customisation
  - Number of registers
- Common Customisation
  - Setting the clock
  - Patient code and others
    - Numeric
    - Alphanumeric
  - Battery type
  - Operating language
  - Entering a heading in the report
  - Selecting the printer type
- Spirometry Customisation
  - Parameters of reference and ethnic factor
  - Observed parameters (FVC, VC, MVV)
  - Graph selection
    - Saving graphs on the database
    - Printing FVC Flow/Volume graph
    - Printing FVC Flow/Time graph
    - Printing VC Flow/Time graph
    - Printing MVV Flow/Time graph
  - Diagnosis selection
  - Comparison mode in POST bronchial dilation
    - Weighted % between PRE and POST
    - % between REF and POST
    - % between PRE and POST
    - Difference between PRE and POST
  - Printout of warnings of Non-Compliant manoeuvres with ATS/ERS criteria
- SpO_2 Pulse oximetry customisation

- Equipment protection customisation
  - Modifying the pin

MAINTENANCE

- Warning selection
  - Period between calibrations
  - Period between maintenance work
- Adjusting the LCD contrast
- TouchPannel calibration
- Checking hardware
- Checking with standard curves (FVC, VC, MVV)
- Others
  - Notifies Programme Update key and allows System initialisation.

OPERATING MODE

- Home
- Hospital

PULSE OXIMETRY

- Test data
  - Patient
    - Code
    - Full name
    - Age, height, weight and sex
- Configuration
  - Average in the SpO_2
- Saving Trends
- Displaying Trends
  - Configuration
  - Signal forwards and backwards
  - Test Parameters
    - Parameter printout
    - Saving parameters on the database

DILATION

- Carrying out Post bronchial dilation test

REPORT

- Printing a report

BLUETOOTH

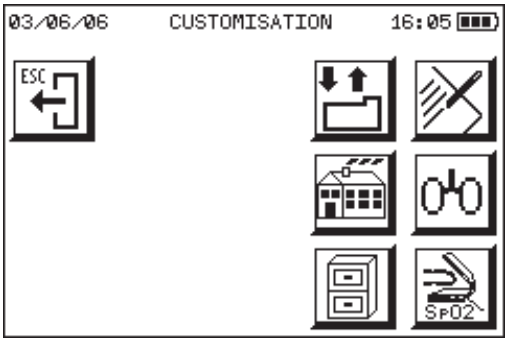
- Enabling or disabling Bluetooth

3.2 EQUIPMENT CUSTOMISATION

Every user should customise the **DATOSPIR MICRO** spirometer according to their requirements due to the variety of options included.

The different options included in the Customisation menu are explained in detail in the previous section.

To access this option, press CUSTOMISATION in the main menu. The following screen will appear:



Exits this screen and goes back to the previous one

Standard Configuration

Home mode customisation

Database customisation

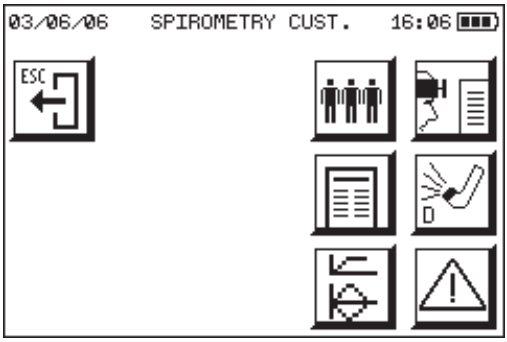
Common customisation

Spirometry customisation

Pulse oximetry customisation

SPIROMETRY CUSTOMISATION

This option customises any suboptions specific to the spirometric tests



Parameters of Reference
Allows selecting among several
Selects for children and adults
Prioritises the age range selected for adults if a different table is chosen for children.
Extrapolates the values for the ages outside the selected table range.

Observed Parameters
Allows for the observed parameters or measured parameters you want to use to be selected. This is only at display level or for the report. All the parameters are saved on the database and can be enabled at any time.

Selecting the graph type

Diagnosis Selection according to:
Miller Quadrant
Snider, Kory & Lyons Algorithm

Mode of comparison between PRE bronchial and POST bronchial
W Average weighted % between PRE and POST
% between REF and POST
% Percentage between PRE and POST
Dif. Difference between PRE and POST

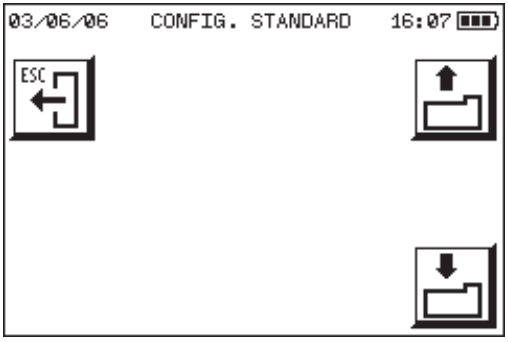
Warnings
Printout of warnings of Non-Compliant manoeuvres with ATS/ERS criteria
Date of latest calibration

CUSTOMISATION OF THE HOME MODE

In this option it is possible to configure the **DATOSPIR MICRO** for use in home mode.
See section **3.13 HOME MODE OPERATION**.

STANDARD CONFIGURATION

This option memorises a user-defined customisation programme status to retrieve it at any time globally and automatically. This option restores the original customisation if it has been modified either voluntarily or inadvertently. In general, this configuration will correspond to that most often used.



Restores the standard configuration

Saves the standard configuration

Follow the instructions below to save the Standard configuration:

1 Customise each of the following options:

Home mode customisation
Database customisation
Common customisation
Spirometry customisation
Pulse oximetry customisation
Protection customisation

as described in this section.

2 Go back to the Standard Configuration option and press the key

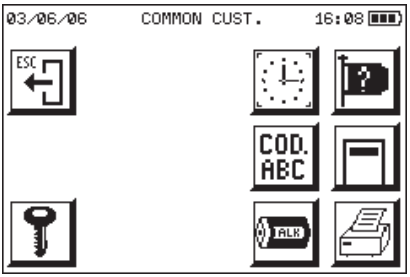
3 Your Standard Configuration has now been memorised.

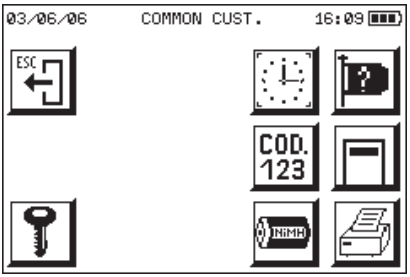
Should you need to modify a customisation option during a test, it can be accessed manually and modified.

The Standard Configuration can be restored at any time. To do so, press the key .

COMMON CUSTOMISATION

This option customises certain suboptions that are common to any test made using the **DATOSPIR MICRO**.





Sets the internal equipment clock (time and date)

or Mode (alphanumeric or numeric)

or Battery type (alkaline or NiMh)
This selection only affects the calculation made inside the equipment to indicate the battery level

Operating language

Enter a heading in the report
This allows inserting two heading lines with a maximum of 33 characters/line. This can include the name of the hospital, the doctor, etc. and will appear in each report.

Printer type

Protection customisation (PIN)

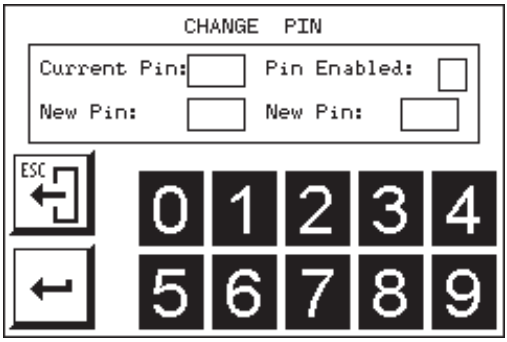
PULSE OXIMETRY CUSTOMISATION

The SpO_2 module is an option included in the **DATOSPIR MICRO**. Each user should customise it to suit their needs.

(See section **3.8 PULSE OXIMETRY TEST PROCEDURE**)

EQUIPMENT PROTECTION CUSTOMISATION

This allows you to change the PIN required to start the equipment (if the protection option is enabled) and to enable or disable equipment protection. The pin code must be of 4 digits.
The following screen appears on accessing this option



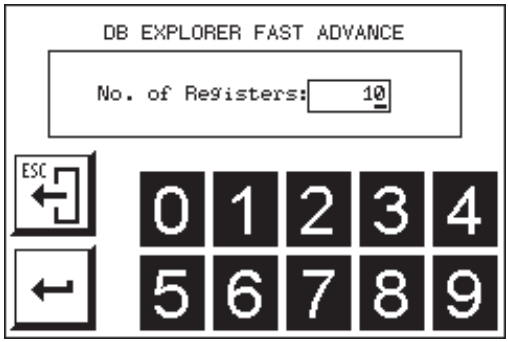
To enable the protection, tick the Pin Enabled checkbox and enter the PIN in the New Pin boxes.

To change the PIN, you must enter the current one in the Current Pin box. If an erroneous PIN is entered three times, the equipment will lock and switch off.

The PIN can be re-enabled by entering the current PIN and unticking the Pin Enabled checkbox.

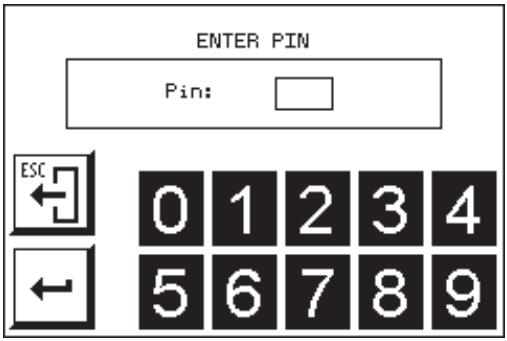
DATABASE CUSTOMISATION

This option allows you to choose the number of registers to be advanced if performing a fast advance using the database search engine.



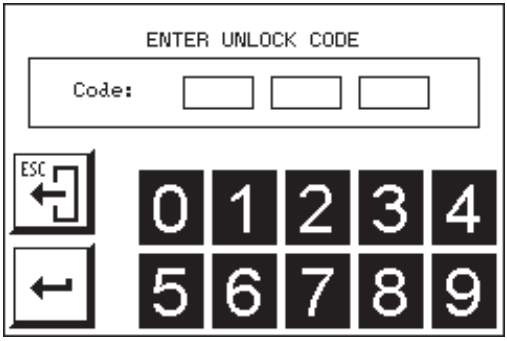
3.3 EQUIPMENT PROTECTION

If equipment protection has been enabled, the following screen will appear when it is started:



Enter the PIN and press ↵ .

If the PIN configured in Equipment protection customisation is entered, access will be given to the **DATOSPIR MICRO** and the main screen will appear.
If an erroneous PIN is entered three times, the equipment will lock and switch off. The following screen will appear when it is restarted:



Enter the unlock code (PUK) supplied upon purchasing the equipment and press ↵ .

If the correct code is entered, the **DATOSPIR MICRO** will unlock and the main screen will appear. From then on, the equipment will return to its initial status (Protection disabled and PIN 0000). If an erroneous code is entered, the equipment will remain locked. This prevents unauthorised access to the equipment and, more specifically, to the private data it contains.

3.4 FORCED VITAL CAPACITY «FVC» TEST PROCEDURE

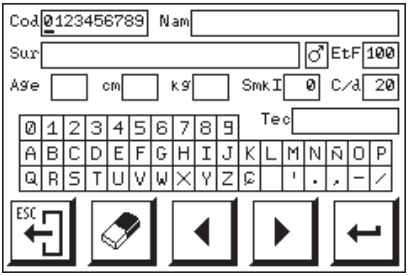
The procedures to be completed to carry out the **Forced Vital Capacity «FVC», slow Vital Capacity «VC» and Maximum Voluntary Ventilation «MVV»** tests are very similar. Therefore, only one detailed description will be given in this section.

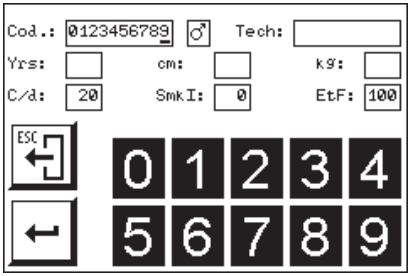
ENTERING PATIENT PARAMETERS

Start the **DATOSPIR MICRO** using the key,

wait for the main screen to appear and press the key FVC

One of the following screens will appear, depending on the mode selected (numeric or alphanumeric):





The meaning of each field is as follows:

Cod (Code): 10-character numeric or alphanumeric field, depending on the customised option, corresponding to the patient code.

Tec (Technician): 10-character numeric field corresponding to the code of the technician carrying out the test.

Yrs (Age): Number corresponding to the age, between 4 and 100.

cm (Height): Height in cm between 50 and 230.

kg (Weight): Weight in kg between 15 and 200.

♂ / ♀ (Sex): Between male and female

C/d (Cigarettes/day):Between 0 and 100 cigarettes.

SmkI (Smoker index): Between 0 and 200 packets a day multiplied by the number of years.
The Smoker Index is the same as the number of cigarettes smoked a day divided by 20 and multiplied by the number of years smoking (cigarettes day x years smoking / 20).

EtF (Ethnic factor): Between 80 and 120% The ethnic factor is used in areas without their own reference parameters and using some which exist but which are corrected to a specific percentage. This factor **MUST BE SET TO 100 IF NOT USED** and can only be modified through the Customisation Programme.

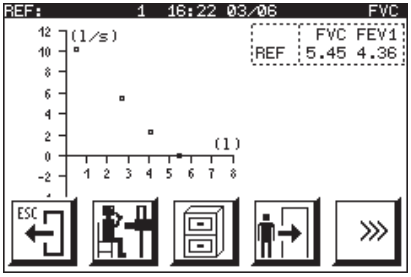
Nam (First name): 20-character alphanumeric field corresponding to the patient's name. This can be omitted if you wish.

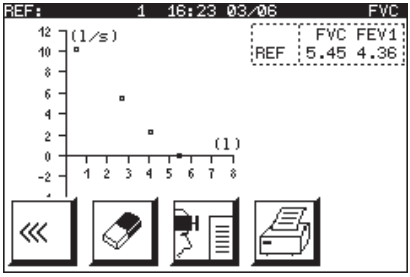
Sur (Surnames): 25-character alphanumeric field corresponding to the patient's surnames. This can be omitted if you wish.

In alphanumeric fields (Forename, Surname, Code, etc.), a **double click** on the field can fully **delete it**.

Enter the patient's details and press the ↵ key to go to the test screen.

ENTERING FORCED VITAL CAPACITY «FVC» TESTS





Go back to the previous screen

Start the manoeuvre

Save the manoeuvre on the database

Modify the patient's details

Next (view the second group of buttons)

Back (view the first group of buttons)

Delete the manoeuvre

Display the manoeuvre diagnosis

Print the manoeuvre report

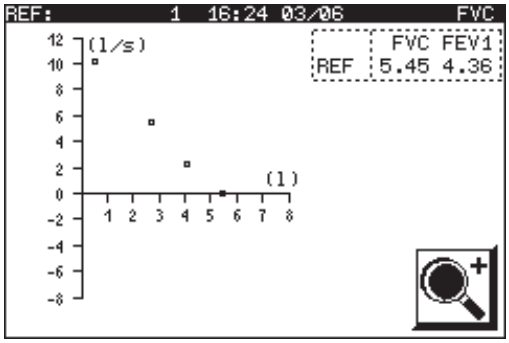
There are other areas of the screen that also have certain functions:

- Pressing on the **axes** changes the type of graph (Flow/Volume or Volume/Time).

• Pressing on the **parameters** displays the screen containing the data on the selected manoeuvre.

• Pressing on a **manoeuvre** selects it. This allows you to see its graph, consult its parameters or print a report.

• Pressing on the **graph** area makes the buttons disappear and makes it larger or smaller.



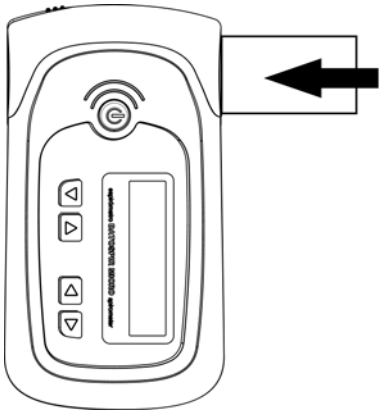
or Makes the graph larger or smaller

• Pressing on the **reference** area (top part of the screen) accesses the patient's details.

The technician who is going to carry out the forced spirometry tests must know the normal procedures required so that the patient can be coached. Otherwise, it is recommended to review documentation on the matter.

When undertaking spirometry, take the following steps into account:

1 Check that the turbine is correctly inserted with the mouthpiece, as in the figure



2 Instruct the patient as to how to the test is being carried out, as his cooperation is vital for it to be completed correctly. Review Chapter **7 SPIROMETRY TECHNIQUE**.
Patients can carry out the spirometry manoeuvres in two different ways:

- The first consists in starting the manoeuvre with **FORCED EXPIRATION** followed by **FORCED INSPIRATION**, if required.

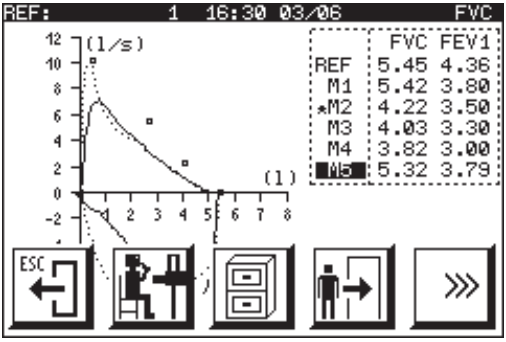
- In the second way the patient breaths normally through the turbine, and when indicated by the technician, takes a deep breath filling completely his lungs, and then performs a **FORCED EXPIRATION** followed by **FORCED INSPIRATION**, if required.

3 Inform the patient of how to hold the equipment when using the spirometer, taking care not to press any key and fitting the nose clip.

4 Press the key and wait until a **flashing arrow** appears on the screen. Then start the spirometric manoeuvre.

The manoeuvre underway can be ended at any time by pressing the key .

The equipment is held so that the doctor can see the screen while the patient is carrying out the tests.



* : indicates the current manoeuvre

M5 : indicates the selected manoeuvre
(the best is selected by default - M1)

At the end of the manoeuvre, one or more of the Warnings, if enabled in the Customisation Programme, may appear to warn whether the manoeuvre is compliant with ATS/ERS Criteria.

According to the indication, the manoeuvre has not been carried out according to one of the following ATS/ERS criteria:

ET - Indicates that spiration has not completed satisfactorily, as the variation on volume in the last second of the manoeuvre was above 25 ml, or the manoeuvre has lasted less than 6 seconds (in patients aged over 10 and more) or less than 3 seconds (in patients aged 10 or less).

EX - Indicates that the start of expiration was not satisfactory, as the extrapolated volume is above 5% of the FVC or 0.15 litres. The ATS/ERS recommends it be less than 5% of the FVC or 0.15 litres, whichever is highest.

The technician performing the spirometry may, where considered appropriate, disable these warnings in the Customisation Programme. In this case, they will also be removed from the printed report.
This disabling is only at display level. The warnings are still taken into account when ordering the manoeuvres.

ATTENTION: Check in the Customisation Programme that the REFERENCES and the ETHNIC FACTOR are suitably selected. The ethnic factor modifies the value of the References according to the percentage selected. 100% is equivalent to the unmodified standard value of the References.

5 Perform new spirometric manoeuvres.

• The new graph is superimposed to compare it with the best (M1/ dotted line) of those saved.

• As many manoeuvres as required can be carried out. The **DATOSPIR MICRO** will always save the five best for FVC and VC and the three best for MVV, according to **ATS/ERS criteria (*)**.

• The different regulations recommend at least three satisfactory manoeuvres in which the repeatability criterion is complied with but no more than eight, as this would tire the patient.

• The last manoeuvre entered remains flashing and corresponds to the continual line graph. Where more than five manoeuvres have been entered and none are flashing, this indicates that the last entered is worse than the five saved and will be deleted.

• If three or more manoeuvres have been completed and the **FVC and/or FEV1** signs are flashing, this indicates that the **repeatability criterion** for one or both parameters has been met, according to the ATS/ERS. This criterion indicates that the best two observed values of FVC and the best two of FEV1 differ in no more than 150 ml if the FVC is greater than 1 litre or in no more than 100 ml if the FVC is below or equal to one litre.

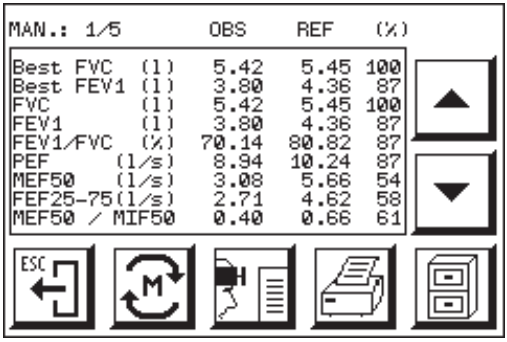
NOTE: Remember that by using the back key

it is possible to go backwards in the menu without losing the information available to date, unless you change patient by entering a new code or on another occasion, although this is previously indicated on screen.

(*) ATS/ERS criteria:
The manoeuvre with least warnings is considered the best (ET, EX). With the same number of warnings, the manoeuvre with the highest value sum of FVC+FEV1 is considered the best.

DISPLAYING RESULTS

Press the parameter area. The data on the selected manoeuvre will be displayed (M1 by default).



Go back to the previous screen

Change manoeuvre

Display the diagnosis of the selected manoeuvre

Print the report on the selected manoeuvre

Save the selected manoeuvre in the database

or

Display the remaining parameters, if selected

• The screen displays the values of Reference, the Observed values and the % between both parameters selected in the Customisation Programme. If an * appears after the REF test, this means that the values of reference have been extrapolated.

- It also displays:

- The best FVC and FEV1 values that may correspond to different manoeuvres.

- Ethnic factor (if not used, this must be 100)

- Warnings of Non-Compliance with ATS/ERS criteria for each manoeuvre

WARNING:
As indicated, the BEST manoeuvre is set at M1. Therefore, use M1 to display the diagnosis, to print the report or to save the manoeuvre for the POST bronchial dilation or for the Internal Database, except where the user considers it wise to choose a different one.

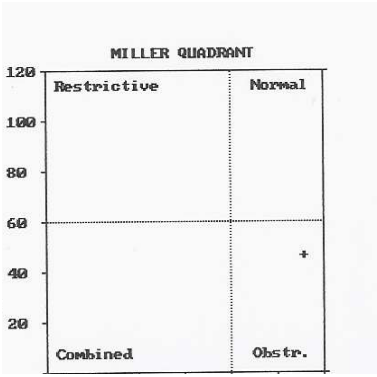
TYPE OF DIAGNOSIS

The **DATOSPIR MICRO** spirometer has two types of diagnosis that can be selected in the Customisation Programme.

NOTE:
If you do not agree with these two criteria, do not use them as a reference.
The diagnosis and the results of the test must always be validated by the specialist.

- **Miller Diagnosis**

This presents the following information **NORMAL, RESTRICTIVE, OBSTRUCTIVE or COMBINED**, according to the criteria of the following chart



- **Snider, Kory & Lyons Diagnosis**

This is based on the following criteria:

If FVC > 80% of the FVC Reference
and FEV1 > 80% of the FEV1 Reference
Values in the range of reference. Normal Diagnosis

If FEV1/FVC% < FEV1/FVC% Reference
and FEV1 < 80% of the FEV1 Reference
Obstructive ventilatory defect
FEV1 < 80 % Slight
FEV1 < 65 % Moderate
FEV1 < 50 % Intense
FEV1 < 35 % Very Intense

If FEV1/FVC% < FEV1/FVC% Reference
and FVC < 80% of the FVC Reference
Non-obstructive ventilatory defect
FVC < 80 % Slight
FVC < 65 % Moderate
FVC < 50 % Intense
FVC < 35 % Very Intense

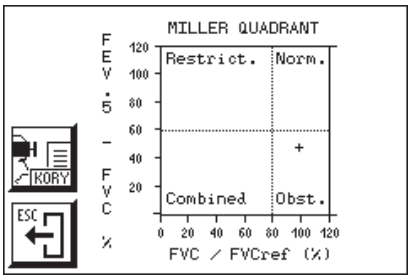
If FEV1/FVC% < FEV1/FVC% Reference
and FVC > 80% of the FVC Reference
Mixed ventilatory defect is suspected

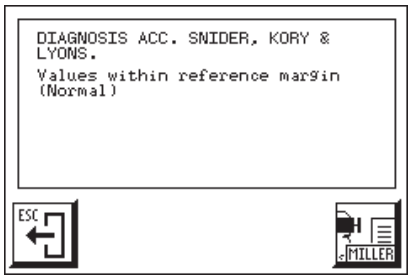
If FEV1/FVC% < FEV1/FVC% Reference
and FEV1 > 80% of the FEV1 Reference
Mixed ventilatory defect is suspected

If the POST bronchial dilation test is carried out
and the FEV1 POST exceeds the base FEV1 or PRE by 15%
There is a positive response to the bronchial dilating drug

To see the diagnosis of the selected manoeuvre, press the key

One of the following screens will appear, depending on the customised diagnosis:





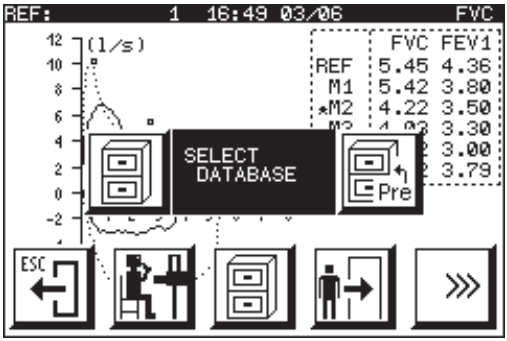
By pressing or , respectively, you can change diagnosis.

MEMORISING FVC TESTS

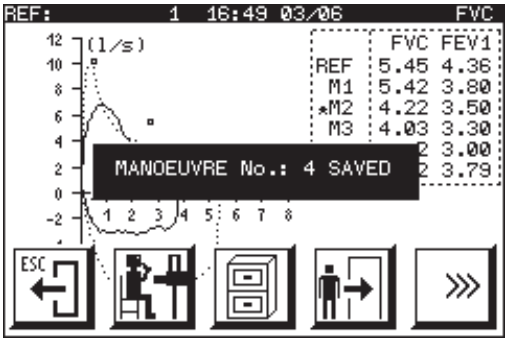
Memorising a test in the Internal Database

The **DATOSPIR MICRO** spirometer has an **Internal Database** that can save different tests which are subsequently transferred to a PC Database.
This base may be of the **«L»** or **«H»**, depending on its capacity.

The manoeuvre selected by default is the best (M1). If you want to save another, it must first be selected.
Once the manoeuvre to be saved on the database has been selected, on the test screen press the key .
The following screen will appear:



Press the key . The following message will appear, indicating that the manoeuvre has been saved:

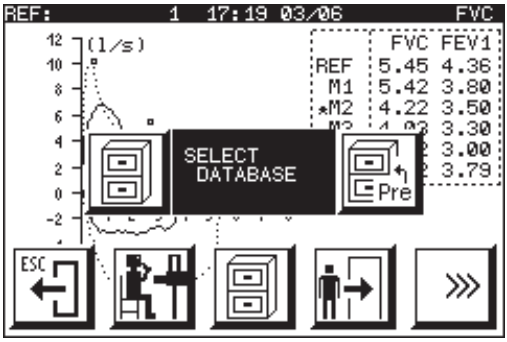


Memorising a test to compare it in POST bronchial dilation mode

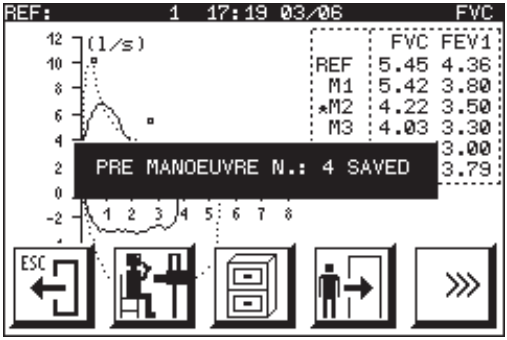
This options allows for a test to be saved in PRE bronchial dilation mode to then compare it with POST bronchial dilation mode.

The process is similar to that described above:

Once the manoeuvre to be saved on the database has been selected, on the test screen press the key .
The following screen will appear:



Press the key .The following message will appear, indicating that the manoeuvre has been saved.



PRINTING THE FVC

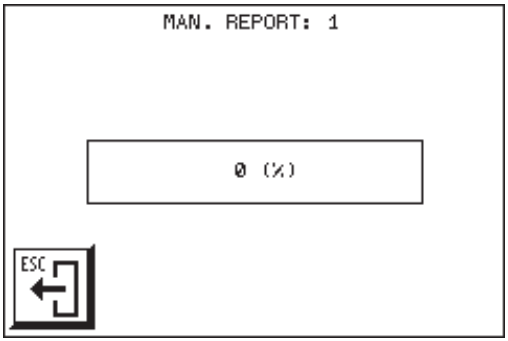
The **DATOSPIR MICRO** spirometer can print any manoeuvre made using an external printer.

The manoeuvre selected by default is the best (M1). If you want to produce a report on another, it must first be selected.

Check that the printer is ready and connected. Select the manoeuvre to be printed (flashing) from the test screen

and press . **The best (M1) is recommended.**

The following screen will then appear to indicate the printing process:



The printer will present a report similar to the one shown on the next page. This will include the parameters and graphs corresponding to the selected curve.
If you do not want graphs, certain parameters, the diagnosis and/or ATS/ERS warnings to appear, disable them as described in section 3.2.

If you want a global printout of the report, including the FVC, VC and MVV tests made on a patient, follow the steps described in the General Report Printout section.

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DATOSPIR MICRO SIBEL S.A.
ROSSELLO 500 08026 BARCELONA

PULMONARY FUNCTION TEST **DATOSPIR MICRO**

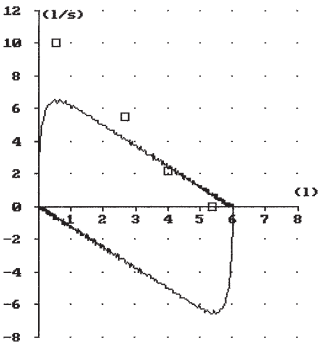
Code: 0000000001 Date: 04/06/2006 Time: 11:34
Name:
Sex: Male Age(y): 27 Height(cm): 174 Wt.(Kg): 68
Temp(°C): 26 Pres(mmHg):760 Humidity(%): 60 Smok. I.: 0
References: SEPAR Ethnic F.(%):100
Reason:
Origin:
Technician:
Bios Ver.: 5115AB-1.00 Prog Ver.: 5115AF-1.00

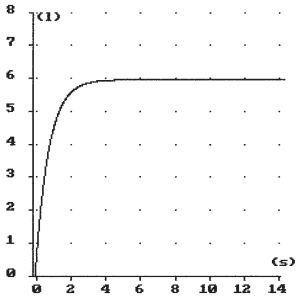
FVC REPORT **MANOEUVRE No.: 1/1**

PARAMETER		OBS	REF	(%)
Best FVC	**(l)**	**5.99**	**5.35**	**112**
Best FEV1	**(l)**	**4.26**	**4.27**	**100**
FVC	(l)	5.99	5.35	112
FEV1	(l)	4.26	4.27	100
FEV1/FVC	(%)	71.17	80.44	88
PEF	(l/s)	6.50	10.11	64
MEF50%	(l/s)	3.78	5.52	68
FEF25%-75%	(l/s)	3.42	4.50	76
FEV1/FEV0.5		1.55	1.45	107
FEV1/PEF	(%)	10.93	6.64	165

Comments: .....

.....





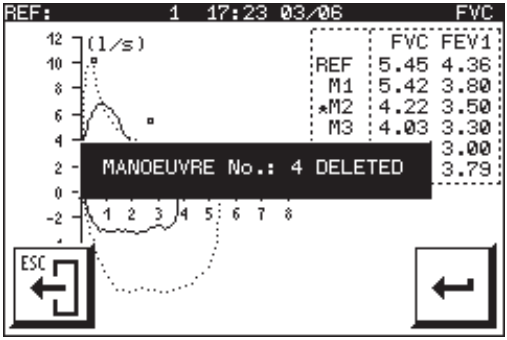
DELETING A MANOEUVRE MADE

The **DATOSPIR MICRO** spirometer deletes any manoeuvre made, whether it is because you are doubtful as to whether its values are correct due to a defective performance, which may distort the results, or for any other reason.

The manoeuvre selected by default is the best (M1). If you want to delete another, it must first be selected.

Select the manoeuvre to be deleted (flashing) from the test screen and press . The following message will appear:

Press the key to delete the manoeuvre. Then the following message will appear to indicate that the manoeuvre has been deleted.



OTHER TESTS ON THE SAME PATIENT

You can do the following after carrying out the FVC test on a patient:

- A **VC** test on the same patient
- An **MVV** test on the same patient
- A **Post bronchial dilation** test on the same patient
- Print the **general report** of all tests on the same patient
- Start the test process on **another patient**.

The spirometer saves the best manoeuvre of each FVC, VC, MVV and/or Bronchial dilation test to print a general report, where required, of them all before going on to another patient.

CHANGE PATIENT

This option is used to change some details of an existing patient or to enter a new patient.

Press the key on the test screen to access the patient's details screen.

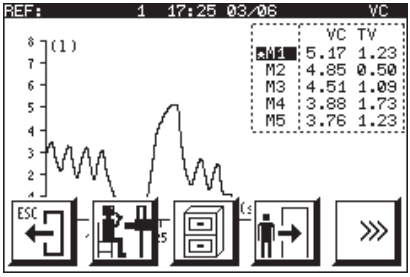
Follow the procedure described in the **ENTERING PATIENT PARAMETERS** procedure to enter the details of a new patient or to modify the details of an existing patient.

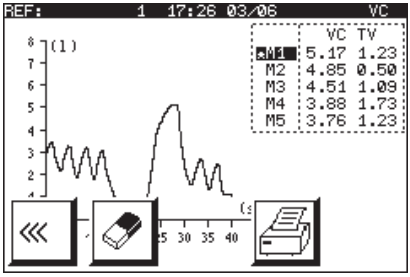
NOTE:
In the event of having modified some details of an existing patient, his parameters will be recalculated taking the changes made into account.

3.5 SLOW VITAL CAPACITY «VC» TEST PROCEDURE

The procedure to carry out the slow Vital Capacity «VC» test is similar to that described in section 3.4 FORCED VITAL CAPACITY «FVC» PROCEDURE with the following variations:

1 Access the «VC» test by pressing the key VC from the main screen and perform a manoeuvre.





2 The axes are always displayed in VOLUME/TIME mode.

3 Instruct the patient as to how to the test is being carried out, as his cooperation is vital for it to be completed correctly.

4 The maximum time allowed for the manoeuvre is **45 seconds**. The equipment saves a maximum of five manoeuvres, ordered according to the VC value, where M1 is the best VC and M3 the worst.

5 To measure the ERV and TV parameters correctly, each manoeuvre must have at least four respiratory cycles.

6 The registering of parameters and graphs is as shown below:

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DATOSPIR MICRO SIBEL S.A.
ROSSELLO 500 08026 BARCELONA

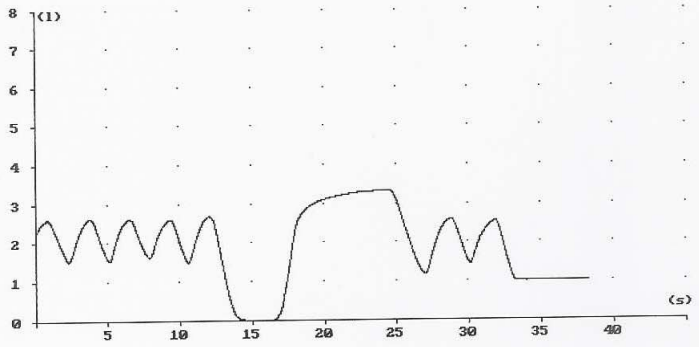
PULMONARY FUNCTION TEST — DATOSPIR MICRO

Code: 0000000001 Date: 03/22/2006 Time: 17:52
Name:
Sex: Male Age(y): 26 Height(cm): 174 Wt.(Kg): 68
Temp(°C): 26 Pres(mmHg):760 Humidity(%): 60 Smok. I.: 0
References: SEPAR Ethnic F.(%):100
Reason:
Origin:
Technician:
Bios Ver.: 5115AB-1.00 Prog Ver.: 5115AF-1.00

VC REPORT MANOEUVRE No.: 1/1

PARAMETER		OBS	REF	(%)
VC	(l)	3.36		
TV	(l)	1.11		
ERV	(l)	0.72		

Comments: .....
.....

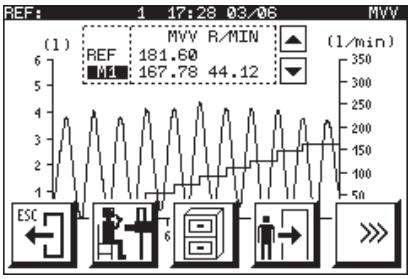


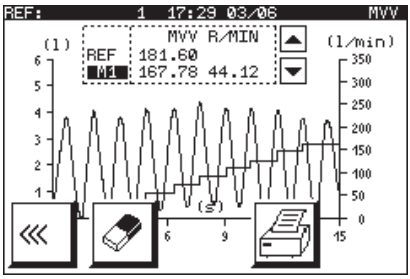
3.6 MAXIMUM VOLUNTARY VENTILATION «MVV» TEST PROCEDURE

The procedure to carry out the Maximum Voluntary Ventilation «MVV» test is similar to that described in section 3.4 FORCED VITAL CAPACITY «FVC» PROCEDURE with the following variations:

1 Access the «MVV» test by pressing the key MVV

from the main screen and perform a manoeuvre.





2 The axes are displayed in VOLUME/TIME mode.

3 Instruct the patient as to how to the test is being carried out, as his cooperation is vital for it to be completed correctly.

4 The maximum time allowed for the manoeuvre is **15 seconds**. The equipment saves a maximum of three manoeuvres, ordered according to the MVV value, where M1 is the best MVV and M3 the worst.

5 The registering of parameters and graphs is as shown below:

Sibelmed®

DATOSPIR MICRO SIBEL S.A.
ROSSELLO 500 08026 BARCELONA

PULMONARY FUNCTION TEST **DATOSPIR MICRO**

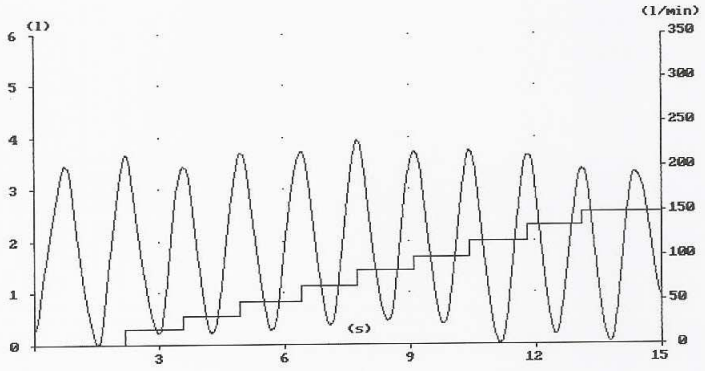
Code: 0000000001 Date: 03/22/2006 Time: 17:52
Name:
Sex: Male Age(y): 26 Height(cm): 174 Wt.(Kg): 68
Temp(°C): 26 Pres(mmHg):760 Humidity(%): 60 Smok. I.: 0
References: SEPAR Ethnic F.(%):100
Reason:
Origin:
Technician:
Bios Ver.: 5115AB-1.00 Prog Ver.: 5115AF-1.00

MVV REPORT **MANOEUVRE No.: 1/1**

PARAMETER		OBS	REF	(%)
MVV	(l/min)	150.82	179.00	84
Br / min		44.12		

Comments: .....

.....



3.7 POST BRONCHIAL DILATOR SPIROMETRY PROCEDURE

The **DATOSPIR MICRO** spirometer allows for Post bronchial dilation tests to be carried out in FVC, VC and MVV provided a test has previously been completed in PRE bronchial dilator mode and saved on the database.

The purpose of this operating mode is to provide PRE and POST spirometric results of applying a bronchial dilating drug in the same report.

The procedure to carry out Post bronchial dilating Spirometry is as follows:

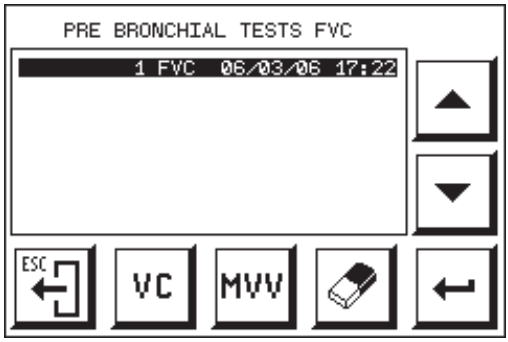
1 Complete a FVC, VC or MVV test on the patient before applying the dilating drug, as described in the previous sections.

2 Memorise the PRE test in the database to compare it in POST mode, as explained in MEMORISING FVC TESTS in section 3.4.

3 Apply the dosage of bronchial dilating drug established by the specialist to the patient and wait for the standardised period.

4 On the main screen, press the key

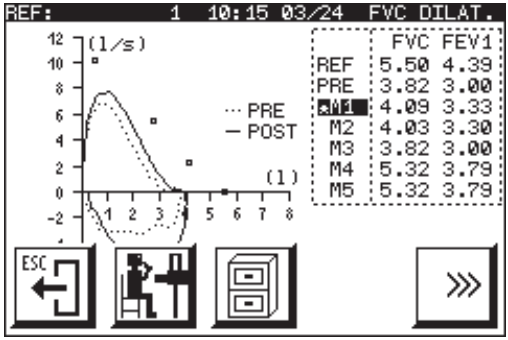
A screen similar to the following will appear, which displays the tests memorised in PRE mode.



Using keys [VC] and [MVV], the VC and MVV tests can be seen, respectively, saved in PRE mode.

5 Select the PRE test with which it is to be compared and press [↵].

The screen then shows the two graphs (PRE and POST) for comparison purposes:



6 Then continue as described in section 3.4 FVC TEST PROCEDURE.

• In this case, the curve in POST bronchial mode is compared with the curve saved in PRE bronchial mode.

• The data screen shows the observed values in PRE and POST mode and the method of comparison between them, depending on the option selected in customisation. See section 3.2 EQUIPMENT PROTECTION.

Weighted % between PRE and POST
% between REF and POST
% between PRE and POST
Difference between PRE and POST

• The most common method of comparison is the **Weighted %**, which corresponds to **%WEIGHT = 100x2(POST-PRE)/(POST+PRE)**.

(See J.E. Cotes: Lung Function Assessment and Aplication in Medicine. Blackwell Sci. 4th Edition 1979, p52-53)

The registering of parameters and graphs is as shown below:

Sibelmed®

DATOSPIR MICRO SIBEL S.A.
ROSSELLO 500 08026 BARCELONA

PULMONARY FUNCTION TEST **DATOSPIR MICRO**

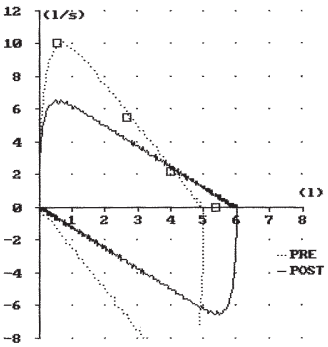
Code: 0000000001 Date: 04/06/2006 Time: 11:34
Name:
Sex: Male Age(y): 27 Height(cm): 174 Wt.(Kg): 68
Temp(°C): 26 Pres(mmHg):760 Humidity(%): 60 Smok. I.: 0
References: SEPAR Ethnic F.(%):100
Reason:
Origin:
Technician:
Bios Ver.: 5115AB-1.00 Prog Ver.: 5115AF-1.00

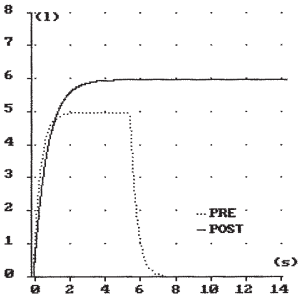
FVC REPORT **MANOEUVRE No.: 1/1**

PARAMETER		PRE	REF	(%)	POST	%P
Best FVC	(l)	5.00	5.35	93	5.99	18
Best FEV1	(l)	4.57	4.27	107	4.26	-6
FVC	(l)	5.00	5.35	93	5.99	18
FEV1	(l)	4.57	4.27	107	4.26	-6
FEV1/FVC	(%)	91.57	80.44	114	71.17	-24
PEF	(l/s)	9.87	10.11	98	6.50	-40
MEF50%	(l/s)	6.16	5.52	112	3.78	-47
FEF25%-75%	(l/s)	5.69	4.50	126	3.42	-49
FEV1/FEV0.5		1.30	1.45	90	1.55	17
FEV1/PEF	(%)	7.72	6.64	116	10.93	34

Comments: .....

.....

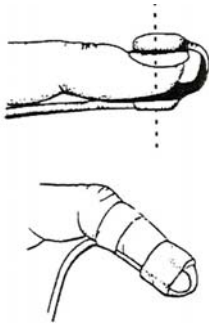




3.8 PULSE OXIMETRY TEST PROCEDURE

Occasional **Oxygen Saturation** (SpO_2) and **Pulse Rate** (PR) tests or long-term studies particularly aimed at controlling patients during sleep or in any other situation (desaturation measurement, etc.) can be performed.

During long-term studies, it is wise to secure the sensor to the patient's finger using a plaster, as shown in the following figure. (The plaster must not place too much pressure on the finger so as not to modify perfusion in the finger).

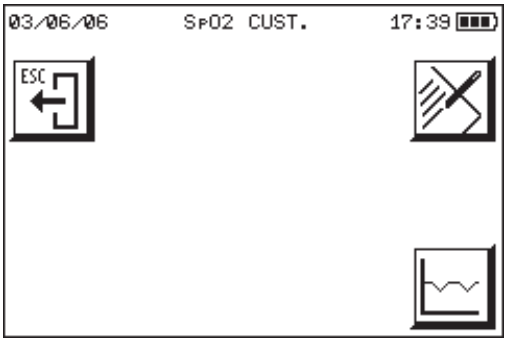


PULSE OXIMETRY CUSTOMISATION

The SpO_2 module is an option included in the **DATOSPIR MICRO**. Each user should customise it to suit their needs.
To access the pulse oximetry customisation menu, start

the **DATOSPIR MICRO** using the key .

Press and .

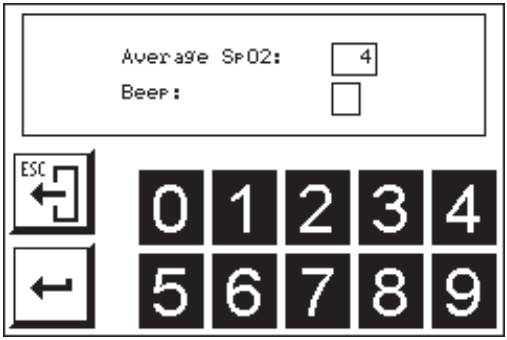


Exits this screen and goes back to the previous one

Average SpO_2 configuration and beeping sound

Parameter configuration Trends graph

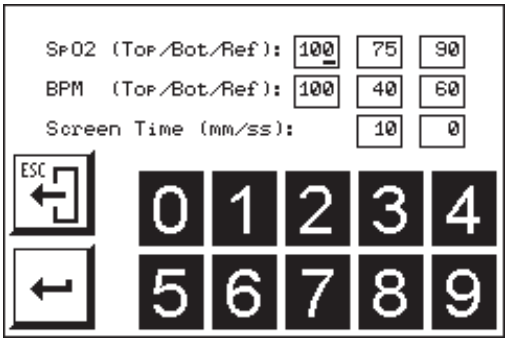
Press and the following screen will appear:



You can:

- Configure the average SpO_2
- Enable the beeping sound (signal coinciding with each pulse)

Press and the following screen will appear:



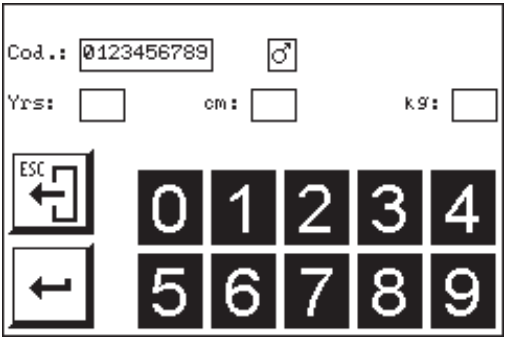
This screen allows you to customise the different pulse oximetry parameters:

- Top (Top) and bottom (Bot) levels fro displaying SpO2 and PR trends.
- Reference (Ref) line level for both channels.
- On-screen display time (between 5s and 29m 59s).

ENTERING TEST DATA

Start the **DATOSPIR MICRO** using the key, wait for the main screen to appear and press the key .

The following screen or similar will appear, depending on the mode selected (numeric or alphanumeric):



The meaning of each field is as follows:

Cod (Code): 10-character numeric or alphanumeric field, depending on the customised option, corresponding to the patient code.

♂ / ♀ (Sex): Between male and female

Yrs (Age): Number corresponding to the age, between 4 and 100.

cm (Height): Height in cm between 50 and 230.

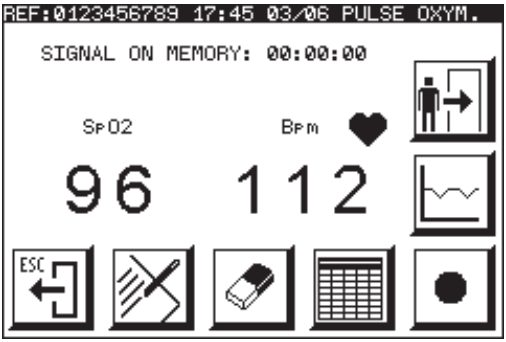
kg (Weight): Weight in kg between 15 and 200.

Enter the patient's details and press the ↵ key to go to the test screen.

PERFOMING PULSE OXIMETRY TESTS

On accessing this screen, the pulse oximeter automatically begins to take samples. The Oxygen Saturation (SpO_2) and Pulse Rate (PR) values are displayed.

The top of the screen indicates the signal time (trends) saved in the memory to date.



Exits this screen and goes back to the previous one

Average SpO_2 configuration and beeping sound

Deletes the study from the memory

Calculates and displays the value of the parameters

Starts or stops saving a study

Accesses the Trends screen

Accesses the patient details screen

- SPECIFIC TESTS

In specific pulse oximetry studies, the screen will indicate the SpO_2 and PR values according to the average configured.
In order to print the results, you must first save the signal (by pressing) during the period required and then following the instructions given in the PRINTING AND/OR MEMORISING ON THE DATABASE section.

- LONG-TERM TESTS

In long-term tests, press the same button to begin saving. A flashing message ("SAVING") will appear in the centre of the screen to indicate that the study is being saved).

It is important to note that the signal is related to the patient code entered. **If the study is started or stopped without having previously changed the patient code or without deleting the study, fragments of signal will be saved one after the other until the 8 hours are completed**. The equipment will interpret that all the fragments correspond to the same patient and the parameters will be calculated on the total memory.

If you want to perform the test on another patient, you must delete the

test (by pressing) and change the patient's details

(by pressing).

To calculate the parameters, press .

If the finger clip is disconnected, the periods in which the SpO_2 and PR value is 0 will not be taken into account when calculating the parameters and the length of the test.

CONFIGURATION

While the oximetry signals are being acquired, it is possible to access the average SpO_2 and beeping sound (signal coinciding with each pulse)
configuration menu.

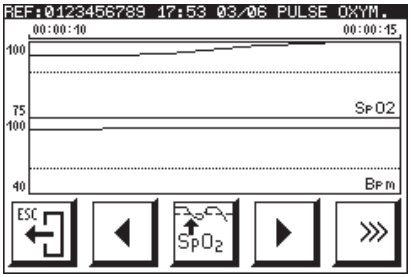
Press and you will access the same screen indicated in

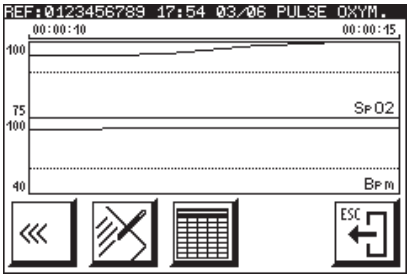
the PULSE OXIMETRY CUSTOMISATION section to modify these two parameters.

DISPLAYING TRENDS

You can only access the trends menu if the study has been saved.

Press





Exits this screen and goes back to the previous one

and Goes back or forwards one page

Locates the next crossing point with the reference line

Displays the other buttons

Configures the trends screen

Calculates and displays the value of the parameters

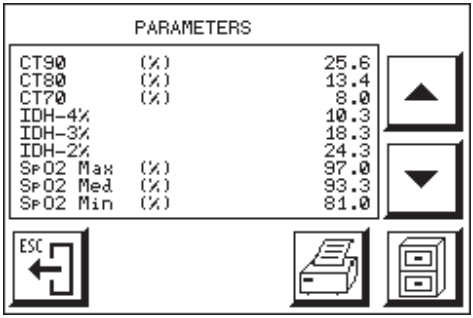
The screen displays the fragment of the SpO_2 and PR signal according to the screen time selected.
The top left shows the relative time at the start of the study (hh:mm:ss).

Each channel allows for a dotted line of references to be displayed that can be selected by the user during configuration. This line may be extremely useful when checking whether the samples exceed a certain value.

PRINTING AND/OR MEMORISING THE DATABASE

The parameters are calculated upon accessing this screen. This option may take a few seconds, depending on the length of the study.

Press the key to access the parameters screen:



Exits this screen and goes back to the previous one

Prints the study report

Saves Parameters on the Database

and Moves around the different parameters

Once a test has been saved on the Database, it can be retrieved in the same manner as any spirometric test.

The parameters calculated to display, print or save on the Database are as follows:

- CT90 % of time in which SpO_2 is below 90%
- CT80 % of time in which SpO_2 is below 80%
- CT70 % of time in which SpO_2 is below 70%
- IDH-4 Desaturation index (>= 4%) per hour
- IDH-3 Desaturation index (>= 3%) per hour
- IDH-2 Desaturation index (>= 2%) per hour

- Maximum SpO_2 Maximum Saturation value
- Average SpO_2 Average Saturation value
- Minimum SpO_2 Minimum Saturation value
- Std. SpO_2 Standard Saturation value
- Maximum PR Maximum pulse rate value
- Average PR Average pulse rate value
- Minimum PR Minimum pulse rate value
- Std. PR Standard pulse rate deviation
- Test Time Useful test time (when the finger clip is disconnected is not considered)

NOTE: Any time during which the finger clip is disconnected is not taken into account when calculating the parameters and Test Time.

To obtain a report on the study performed, press

:

Sibelmed

DATOSPIR MICRO SIBEL S.A.
ROSSELLO 500 08026 BARCELONA

PULSE OXYMETRY TEST **DATOSPIR MICRO**

Code: 0000000001 **Date:** 03/22/2006 **Time:** 18:01
Name:

Sex: Male **Age(y):** 26 **Height(cm):** 174 **Wt.(Kg):** 68

Reason:

Origin:

Technician:
Bios Ver.: 5115AB-1.00 **Prog Ver.:** 5115AF-1.00

PARAMETER		OBS
CT90	(%)	25.6
CT80	(%)	13.4
CT70	(%)	8.0
IDH-4%		10.3
IDH-3%		18.3
IDH-2%		24.3
SpO2 Max	(%)	97.0
SpO2 Med	(%)	93.3
SpO2 Min	(%)	81.0
SpO2 Std	(%)	3.2
BPM Max	(BPM)	125.0
BPM Med	(BPM)	75.6
BPM Min	(BPM)	65.0
BPM Std	(BPM)	12.8

Test Time 02:01:12

Comments: .....

.....

TEST TRANSFER

As with spirometric tests, the pulse oximetry tests saved to the database can be transferred to a PC. Remember that only parameters are saved, not the curve.

PULSE OXIMETRY MEASUREMENTS

It is possible to take pulse oximetry measurements while performing a spirometry test (only in FVC and VC tests).

To do so, the pulse oximetry finger clip must be connected when starting the spirometry.

While spirometry is being performed, the Saturation (SpO_2) and Pulse Rate (PR) value will appear on the screen with the curve and will be saved in the memory. The average of both values will be displayed on completion of the manoeuvre.

The Pulse Oximetry menu must be accessed to retrieve all the measured values from the memory. This will be dealt with like a Pulse Oximetry test saved in the memory.

3.9 CALIBRATION PROCEDURE

GENERAL OBSERVATIONS

The standards in force regarding spirometry recommend that all spirometers be periodically calibrated. This is due to alterations which may modify the characteristics of the electronic circuits and mechanical elements over time and cause a change in the spirometer calibration factors. Hence, a calibration system has been incorporated based on a reference volume signal (e.g. a syringe).

Furthermore, this calibration factor must take the changes in volume associated to atmospheric conditions (temperature, relative humidity and barometric pressure) into account. The most influential factor is temperature, followed by the humidity level.

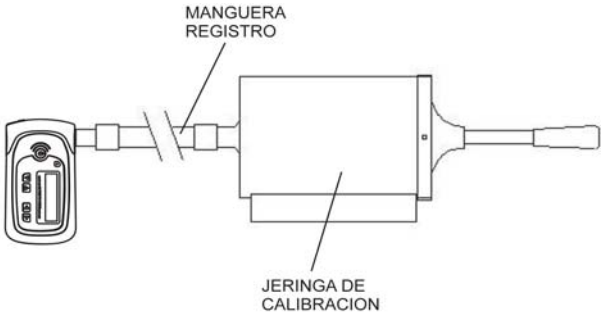
The **DATOSPIR MICRO** includes a Calibration Programme for fast (less than one minute) and easy checking and auto-correcting of deviations in the measurements taken based on a standard or reference volume for the quality control of the different spirometric tests.

The regularity of calibration depends on the user, although the standards recommend it be done on a daily or weekly basis.

CALIBRATION PROCESS

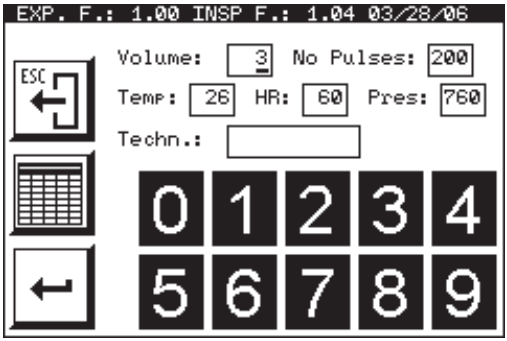
The calibration process is as follows:

1 Install the spirometer and the syringe as in the figure



2 From the Main screen, press the key

The following screen will appear:

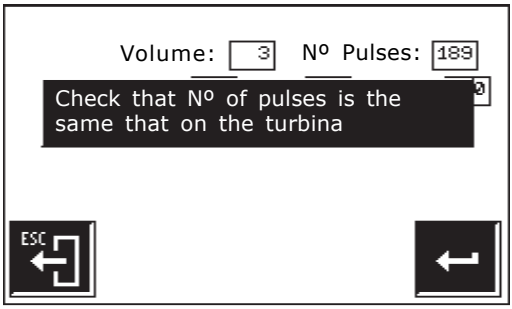


If there are previous calibrations, the details of the last one will appear in the title.
Enter the necessary data:

Volume (volume of the syringe): between 0 and 6 litres, depending on the syringe.
If a 0 is entered, the default factors are used (Fct = 1 and NPulses = 188) and the calibration process is completed.

No. of Pulses(number of pulses): number printed on the turbine that corresponds to the number of pulses/turn.
If the number of pulses associated to its turbine is as appears on screen, continue without modifying it.

If it is different, enter the number of turbine pulses. In this case, the following screen will appear:



Press [↵] and the factors will be calculated and the calibration process completed.

In case of pressing [ESC] the number of pulses will not change and will return to the previous screen.

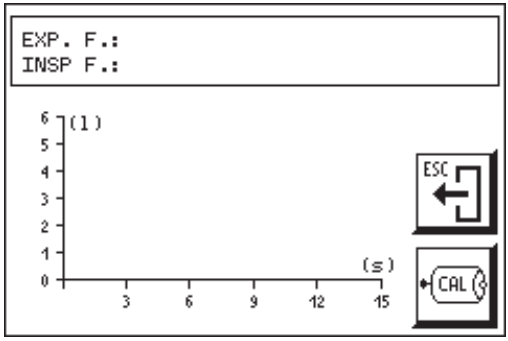
NOTE:
Each turbine is factory calibrated individually and is associated to a factor equivalent to the pulses / litre detected and printed on it. Although dispersion among turbines is within ±3%, it is worth entering this factor in the spirometer if the turbine is changed to obtain the maximum measurement precision.

Temp (ambient temperature in ºC): detected by a sensor inside the equipment. This can be modified if required.

HR (relative humidity in %): entered in the last calibration. This can be modified if required.

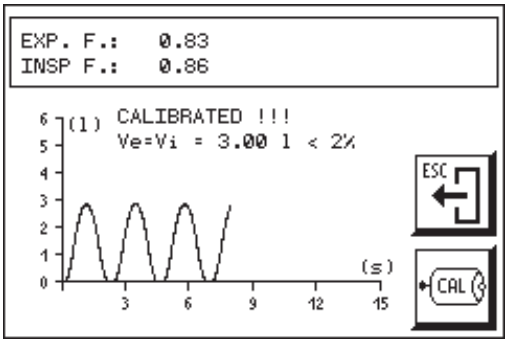
Pres (atmospheric pressure in mmHg):entered in the last calibration. This can be modified if required.

3 Press ↵ . If a Volume other than 0 has been entered and the No. of Pulses has not bee modified, the following screen will appear:



4 Press CAL and start the calibration process emptying the syringe for **two or more consecutive cycles** (one cycle is equal to emptying and refilling the syringe). When emptying and filling, the syringe plunger must move all the volume used as a reference. If this is not done correctly, the equipment will detect it as «incorrect manoeuvres». Furthermore, this process should be completed in a regular and uniform manner, without causing flow rates that are too high or too low. Where this is not the case, you will be told to repeat the manoeuvre.
The time for each cycle must be no less than three seconds and no more than six.

5 The screen shows the expiratory and inspiratory factors taken by the equipment and, if they are within 2%, will consider the system calibrated. Where this is not the case, point **4 is repeated**.



6 Once calibrated, exit the Calibration Programme and access the Spirometry programme to begin the tests.

Note:

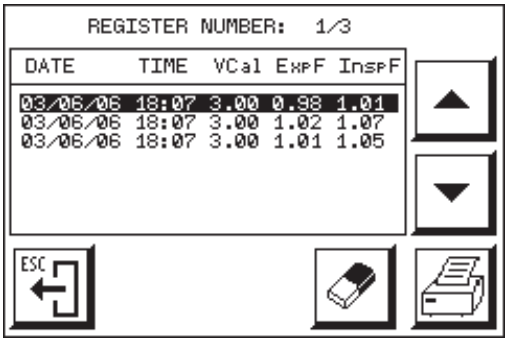
If, upon entering the calibration parameters in point 2, "Calibration Volume (l): 0" is allocated, the system takes the calibration factors "EXP F. and INS F.:1.00", corresponding to original factory calibration. This calibration should only be used as a guideline and in the event of no syringe being available.

CALIBRATION REGISTERING

The spirometer has a register containing the expiratory and inspiratory factors of the **last ten calibrations** performed. This is extremely useful for centres requiring a quality control of the processes they use.

To do so, press on the first calibration process screen.

The following screen will appear:



Deletes a register

Prints existing registers

and Moves around the different calibrations

The information shown is:

- Number of registers available
- Date of calibration
- Time of calibration
- Volume of calibration
- Expiratory factor
- Inspiratory factor

3.10 INTERNAL DATABASE

The **DATOSPIR MICRO** has an Internal Database as standard which saves the different tests made using the equipment and subsequently displays them, prints them and/or transfers them to a PC or other computerised system for storage or management.

The base information remains, even when the equipment is unplugged.

There are two bases with the same functions but different capacities:

Database «L»
Database «H»

The tests that can be saved (using a six-second FVC as reference) are:

Database «L»	**150**
Database «H»	**>1000**

The saving of the tests has already been described in the sections corresponding to each test.

The database always saves all the spirometric parameters of each of the different test modalities, FVC, VC, MVV or Dilation, despite them not being selected in the Customisation programme.

Different functions are possible from the spirometer:

1 Search the database

2 Search for a patient

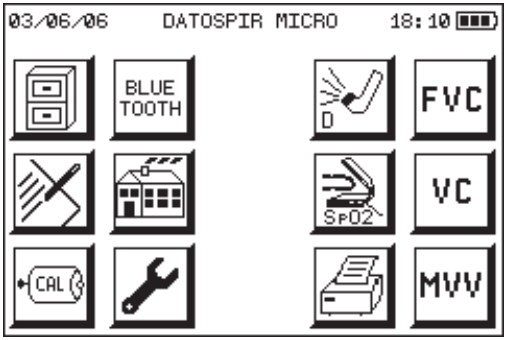
3 Search for a register

4 Print a summarised report

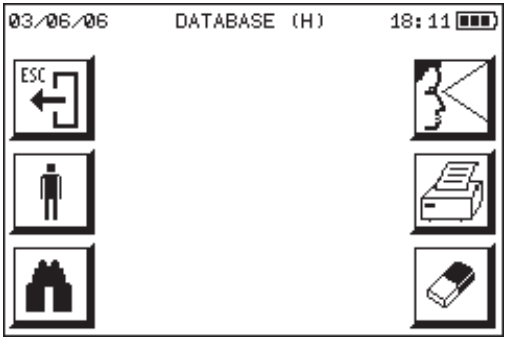
5 Delete the database

To do so, start the **DATOSPIR MICRO** using the

key and wait for the following screen to appear:



Press to access the screen with the options to be chosen with the database.



Go back to the main screen

Search for patient

Search for register

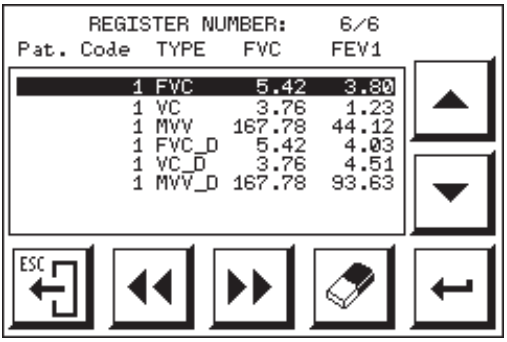
Search the database.

Summarised report

Delete the database.

DATABASE SEARCH

Select the option to display the tests saved on the database



Go back to the previous screen

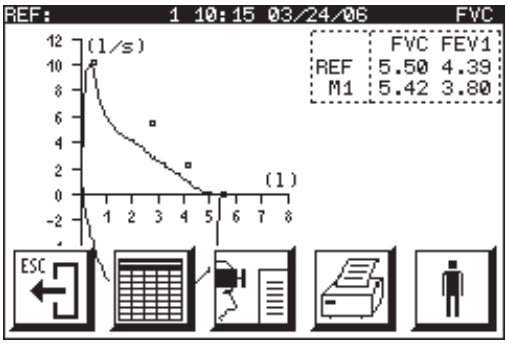
and Fast back/forwards through the registers
The movement value is configured in the Customisation menu.

Deletes the test selected

Displays the test selected

and Moves around the different tests

Select a test and press . The following screen is accessed:



Go back to the previous screen

Display test data

Display the test diagnosis

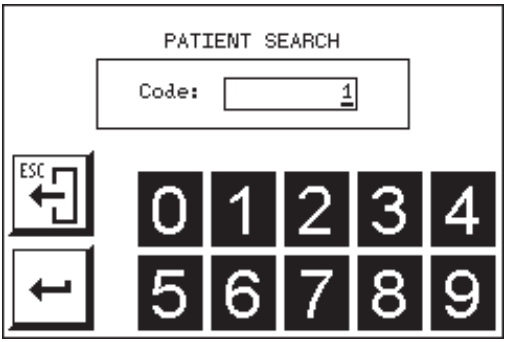
Print the test

• Pressing the axes changes the type of graph (Flow/Volume or Volume/Time).

• Pressing the graph area makes the buttons disappear and makes it larger or smaller.

PATIENT SEARCH

Select the option to search for a patient in the database. The following screen will appear:



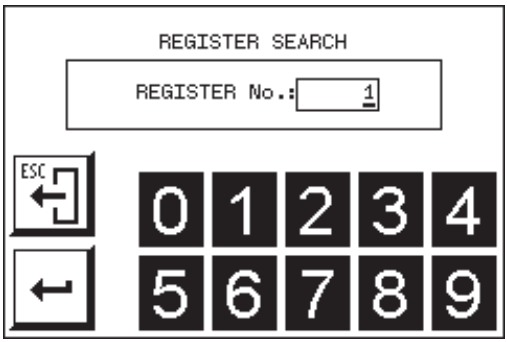
Enter the patient code and press .

If the patient exists, the database search screen will appear. Where this is not the case, the following warning message will appear:
«PATIENT CODE NOT FOUND».

REGISTER SEARCH

Select the option to search for a register in the database.

The following screen will appear:



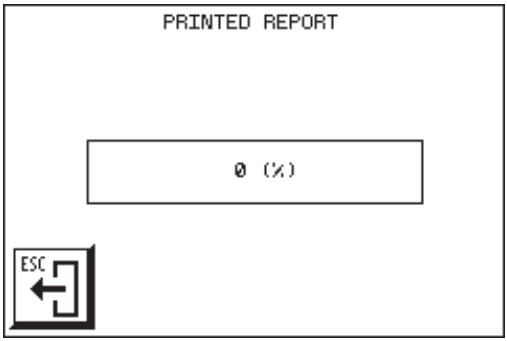
Enter the register number and press ↵ .

If the register exists, the database search screen will appear. Where this is not the case, the following warning message will appear: «REGISTER ID NOT FOUND».

SUMMARISED REPORT

Select the option 🖨 to print a report with the list of tests saved on the database.

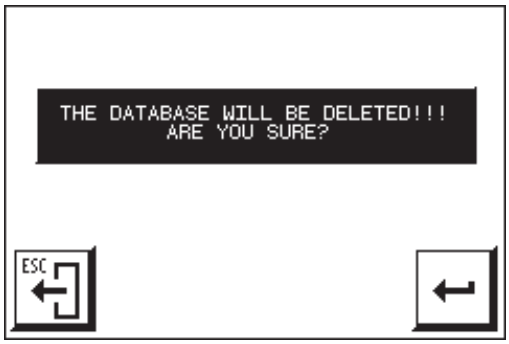
The following screen will appear to indicate the printing process:



DELETE DATABASE

Select the option to delete the database.

The following message will appear:

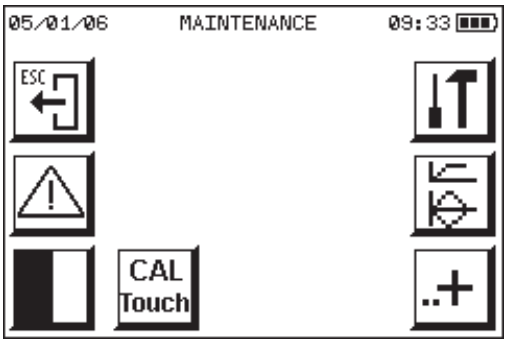


Press to accept and delete the database or press to go back to the previous screen without deleting it.

3.11 MAINTENANCE PROGRAMME

The equipment has a maintenance programme to adjust and/or check the working order of certain options.

From the **Main Menu** screen, press



Enables the calibration and/or maintenance warnings

Adjusts the screen contrast

TouchPannel calibration

Auto-checks the equipment

Checks with pre-saved standard curves

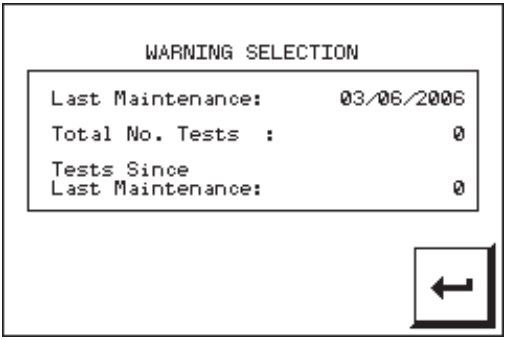
Equipment configuration

WARNINGS

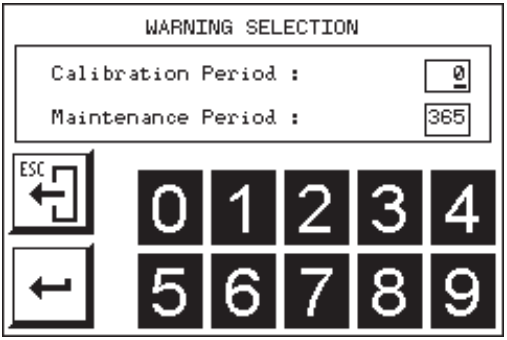
Select the option .

The following screen will appear with the information on the

latest maintenance work, the tests performed and the tests performed since the last maintenance work.



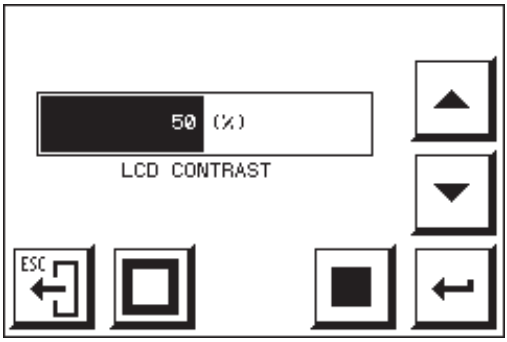
Press .



This screen defines the periods in days between calibrations or between preventative maintenance work on the equipment.
If the days specified without calibration or maintenance are exceeded, the equipment warns of such by displaying a sign every time it is started. If 0 days is entered, a warning is never given.

LCD CONTRAST

Select the option to configure the screen contrast.



Go back to the previous screen

Black background/white content

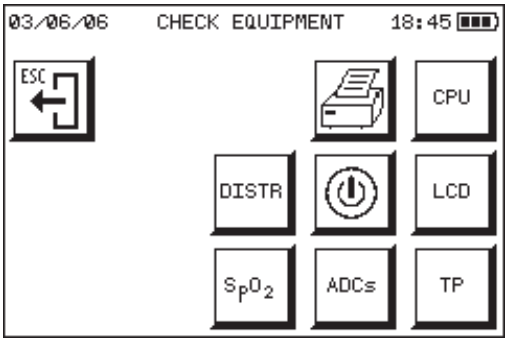
White background/black content

Validate choice

and Increase/decrease contrast

EQUIPMENT CHECK

Select the option to check different parts of the equipment.



Go back to the previous screen

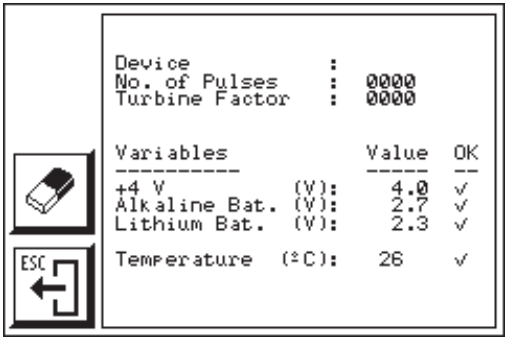
Distributor details

Pulse oximetry module

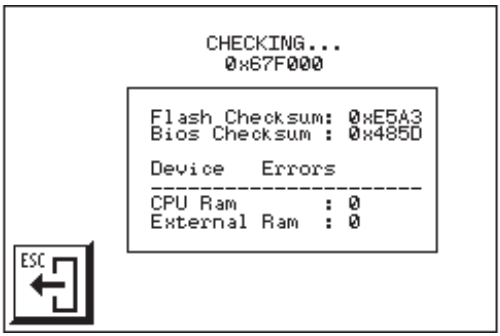
Check the external printer selected.
The SIBELMED logo, the heading lines and 10 lines of characters will be printed.

Check that the automatic on and off work properly. Upon selecting this option, the equipment switches off and on automatically after 5 seconds.

Display the values of different variables (No. pulses, Turbine Fct, Alk. B., Li. B., etc.). This indicates whether the read value is correct.



CPU check.
This calculates the Flash programme checksum and the Bios programme checksum. It also indicates whether there are errors in the RAM memory of the CPU and in the external RAM.

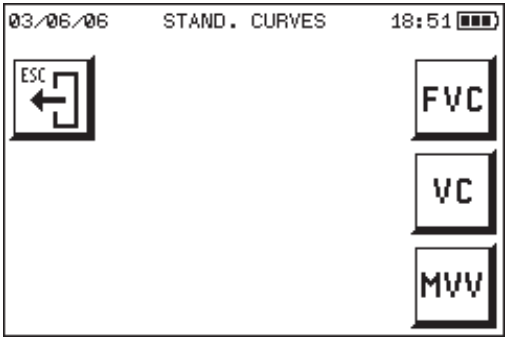


LCD — Performs a test on the LCD. Follow the instructions given on the screen.

TP — Touch Screen

STANDARD CURVES

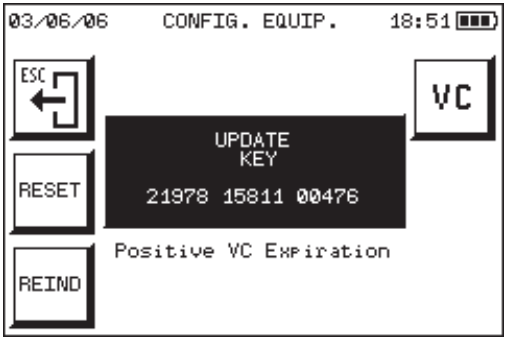
Select the option to check the working order of the equipment through certain pre-saved curves.



Select the curve type and follow the instructions on the screen, which are similar to the FVC, VC and MVV procedures. With these curves you can operate the equipment as if they were real patient curves, with slight exceptions.

EQUIPMENT CONFIGURATION

Select the option to configure different options of the equipment.



Go back to the previous screen

Reset all equipment variables.

Reindex the database.

Change from positive VC to negative VC and vice versa

- An **updating key** is also displayed, which is necessary for updating the equipment and obtaining a new, improved version of it.

3.12 UPDATING INTERNAL SOFTWARE

The **DATOSPIR MICRO** spirometer has two types of internal software:

- **Bios** (basic hardware control programme)
- **Flash** (programme containing all the equipment options)

The update option allows for the version of Bios and/or Flash to be updated without having to take the equipment to the factory and without having to open it.

WARNING
Both updates are completed through the serial port (RS232)

BIOS UPDATE

The updating process for the BIOS programme is as follows:

1 Run the **W-20 Spirometry Software** and access the Configuration - Hardware Test option.
Run a communications test to check that the connections are correct.

2 Switch the equipment off.

3 With the **DATOSPIR MICRO** switched off, remove the rear cover, disconnect the Bluetooth (where applicable) and turn both switches ON.

WARNING
This option should be carried out by an expert or specialist.

4 Turn the equipment and support it on the table with the screen visible.

5 Press the On-Off key for 1 second and release it. Nothing will appear on the screen.

6 Copy the Bios file (DMBios.tsk) into the **\FIRMWARE** directory of the application (W20).

7 Run the **W-20 Spirometry Software**, access the Configuration - Links option and check that the DATOSPIR MICRO is selected.

8 Access the Configuration - Utilities - Update Bios option.

9 Follow the instructions on screen and wait for the process to end.

10 Once completed, turn both updating switches OFF again, replace the Bluetooth (where applicable) and close the cover.

FLASH UPDATE

Flash can be updated for a new version of the programme (in which improvements have been included) or to add another option to the equipment (dilation option, Bluetooth, etc.).

In the case of the latter, SIBEL, S.A. will provide a new update key.

In the case of the former, consult the key in the equipment before starting the update process:

Switch the **DATOSPIR MICRO** on and, from the main menu, select .

Select and consult the update key that appears on the screen.

Switch off the **DATOSPIR MICRO**.

The updating process is as follows:

1 Run the **W-20 Spirometry Software** and access the Configuration - Hardware Test option.
Run a communications test to check that the connections are correct.

2 Switch off the **DATOSPIR MICRO**.

3 Start the **DATOSPIR MICRO** while keeping the top right of the screen pressed down. This runs the programme in BIOS to update FLASH.

4 The BIOS **access key** (press 3 and then 4) is then requested to prevent any user from accessing it by mistake.

5 Copy the new file provided by SIBEL containing the update (DMFlash.tsk) to the **\FIRMWARE** directory of the application (W20).

6 Run the **W-20 Spirometry Software**, access the Configuration - Links option and check that the **DATOSPIR MICRO** is selected.

7 Access the Configuration - Utilities - Update Flash option (the W-20 Spirometry Software in demo mode provided upon purchasing the equipment is enough).
A dialogue box will open where the **update key** (the one previously consulted if this is a version update or the one provided by SIBEL if it is an option update) must be entered.

8 The new programme will be transmitted. The process may take around 10 minutes, depending on the PC.

9 Switch off the **DATOSPIR MICRO**.

3.13 HOME MODE OPERATION

The **DATOSPIR MICRO** spirometer is very useful for monitoring and controlling asthmatic patients or others to suit the specialist's criteria, whether they are at home or in hospital.
With this option, the spirometer is extremely user-friendly equipment, as the sequence of instructions on-screen will guide patients during spirometric manoeuvres. At the same time, it automatically saves the best manoeuvres made in the different tests in the memory. This enables the specialist to subsequently analyse them and make the corresponding diagnosis.
It is also possible to transfer them from the equipment Database to the PC Database using **W20 Spirometry Software**.

Three stages can be described for a better understanding of this operating mode:

1 Spirometer configuration
2 Acquisition of spirometric tests
3 Displaying of the information saved

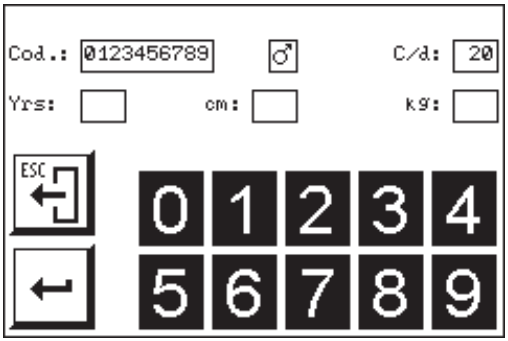
CONFIGURATION

The specialist must configure the spirometer in **HOME** mode and provide the patient with the necessary instructions. The process to follow is as described below:

From the main screen, press and then press .

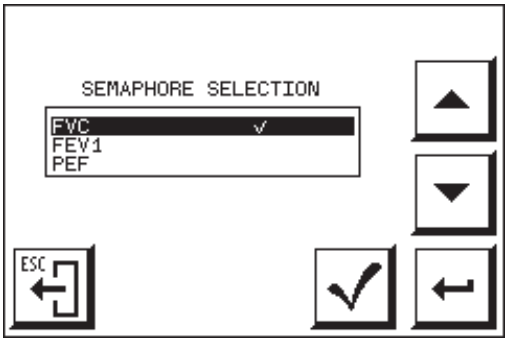
Home mode customisation includes the customisation of the patient's details and the test data.

Press and enter the patient's details.



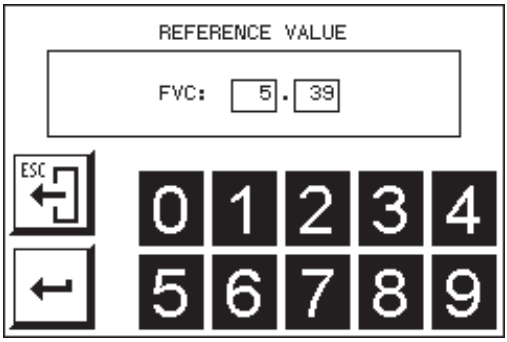
Code: xxxxxxxxxx	Between 0 and 9999999999
♂ / ♀ (Sex):	Between male and female
C/d: xxx	Between 0 and 100 cigarettes/day
Age: xx	Between 4 and 100
Cm: xx	Between 50 and 230 cm
Kg: xx	Between 15 and 200 Kg

Press to configure the semaphore and the alarms.



Select the parameter of reference for the manoeuvres and press

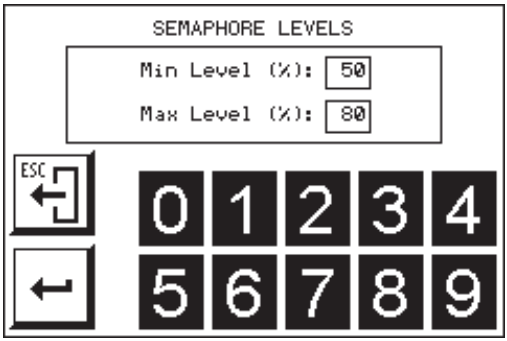
The value of **REFERENCE** will then appear, depending on the age, weight, etc. of the patient and the tables enabled in the Customisation programme. This value can be changed by the specialist for patients who, under controlled asthma conditions, have a significant deviation with regard to the reference standard. The value programmed will be equivalent to **100%** in the subsequent control. Select the value, where necessary.



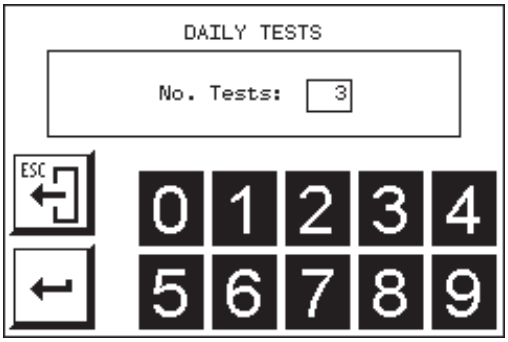
The levels must be defined in percentages in relation to the value previously selected from among the different semaphore indicators. The standard levels are:

GREEN Zone	**Between 100% and 80%**	**Normal**
YELLOW Zone	**Between 80% and 50%**	**Precaution**
RED Zone	**Between 50% and 0%**	**Warning**

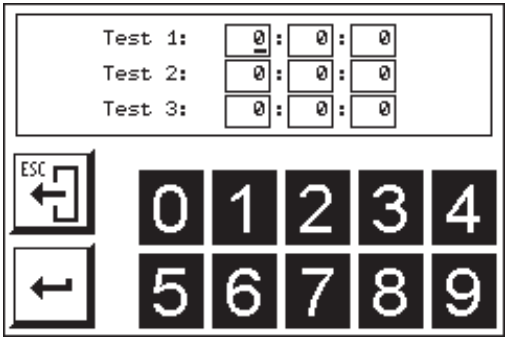
Select the level, where necessary.



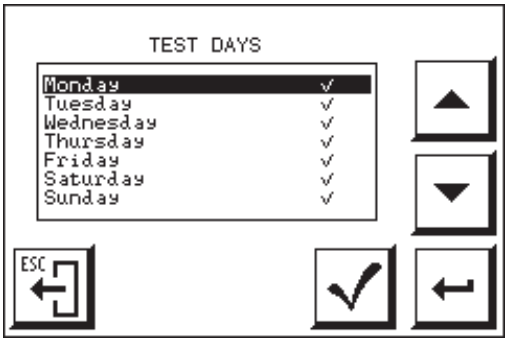
The alarms are a reminder for the patient, as the test can be taken at any time, despite it being different to the time programmed, and the time it is taken is recorded.



Programme the alarms for each test.



Select the days of the week on which the tests are to be performed.



Home mode is now configured, so that
you simply have to press on the main screen to enable it

and to switch off the equipment.

ACQUISITION OF SPIROMETRIC TESTS

Once the equipment has been configured by the specialist the test acquisition process can begin.

The storage capacity is 150 or 1000 tests, depending on the database ('L' or 'H').

The specialist will explain the test to the patient, particularly the forced expiration manoeuvre process, the equipment operating sequence and when the tests should be taken.

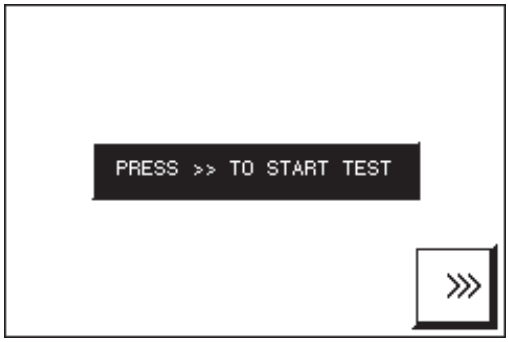
The operating sequence is as follows:

If **start-up** is **manual** (the patient starts the equipment):

1 The start screen will appear along with the model, the programme version and the bios version, the date and the time.

If **start-up** is **automatic** (because it is the time programmed in Alarms):

1 The equipment will start up and the start screen will appear along with the model, the programme version and the bios version, the date and the time.
The following screen will then appear:

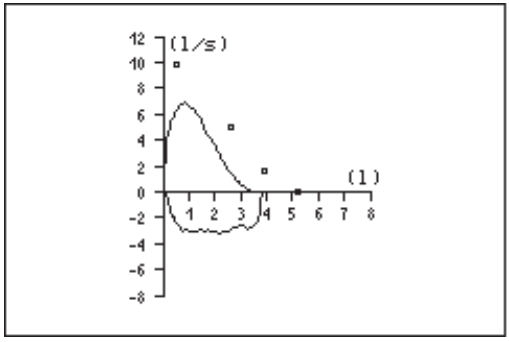


and the equipment will issue a beeping sound every 10 seconds.

If, for **2 minutes**, the equipment is not pressed, it will switch off.

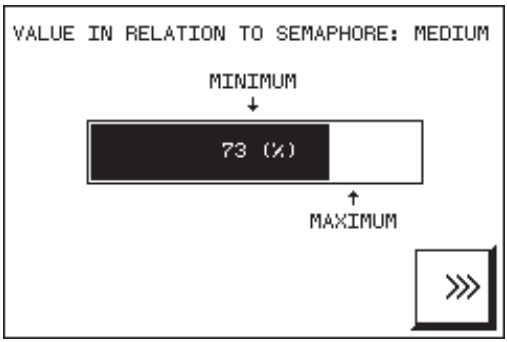
Press the key .

2 The following screen will appear:



The patient can start the manoeuvre after the arrow has appeared (they have **30 seconds**).

3 The patient must perform three expiratory manoeuvres and the following screen will appear:



Indicates the value of the manoeuvre in relation to the semaphore (low, medium or good).

The equipment automatically saves the best manoeuvre in the memory, according to the following criteria:

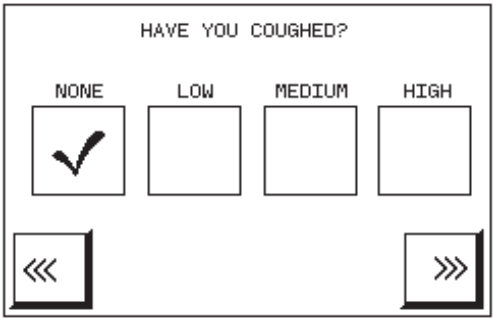
- The one with the best sum of FVC + FEV1 is considered the best.
- The one with the best FVC is considered the best.
- The one with the best FEV1 is considered the best.
- The curves with warnings (ET, EX) are considered the worst.

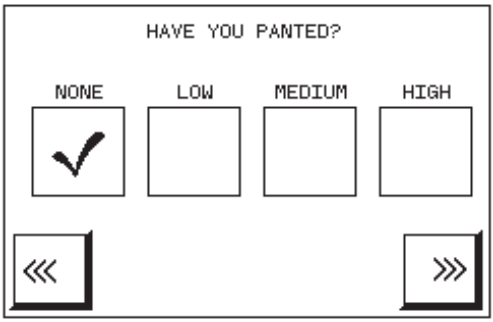
4 As a guideline for subsequent control and diagnosis, patients can note down, where applicable, one or several of the different symptoms during the test (COUGH, PANTING, BREATHING DIFFICULTIES or MUCOSITY).

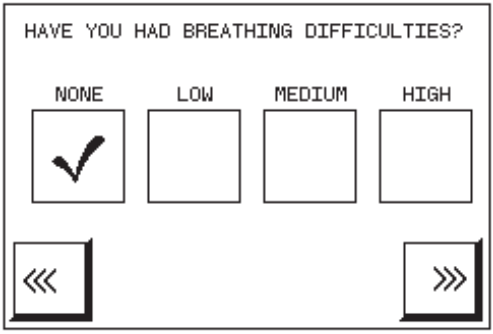
The severity can be chosen for each symptom from among the following values:

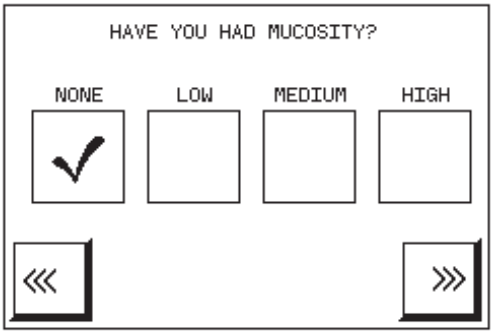
- NONE (No symptom)
- LOW
- MEDIUM
- HIGH

To do so, press » to go to the next screen or « to go back to the previous screen:









Upon pressing the following screen appear, indicating that the test has been saved on the database:

IMPORTANT NOTE

Proceed as follows to go from HOME MODE to HOSPITAL MODE:

For equipment with the key **.**

Keep the lower right of the screen pressed down

and restart by pressing **.**

The following warning will appear on screen after a few seconds: «RELEASE THE KEYS». Then release the lower right of the screen.

The spirometer is now in HOSPITAL mode.

DISPLAYING SAVED INFORMATION

The information saved can be displayed on the **DATOSPIR MICRO** spirometer or on the PC using the **W20 Spirometry Software**. In both cases, the aforementioned options can be chosen (consulting parameter, printing a report, etc.).

4. COMMUNICATIONS SYSTEM

One of the great qualities of the **DATOSPIR MICRO** is its Communications System, with other means that enable it to:

Transfer Equipment Checking Data
Updating Internal Software
Transfer Tests on patients to a PC
Export Tests on patients to other Management Systems

Communications can be made through three different channels using the corresponding software:

- RS232C Series (standard)
- USB (standard)
- Bluetooth (optional)

To install USB and Bluetooth, consult the **W20 Spirometry Software User's Manual**.

4.1 TRANSFERRING EQUIPMENT CHEQUE DATA AND DATABASE DATA

The **DATOSPIR MICRO** includes a programme that auto-checks the working order of certain parts of the equipment, displaying the information on the screen and saving it in an internal file.

The information available is:
Hardware check
Software check
Equipment customisation
Calibration Registering
FVC test with standard curve

If a problem is detected that the user is unable to solve, the first alternative is to send the auto-check information to the **SIBEL S.A.** After-sales Service or to your distributor, who will analyse it and assess the cause of the problem, providing or proposing a suitable solution.

W20 Spirometry Software (in demo mode or enabled) **is required to transfer this information**. The programme in demo mode is included as standard with the equipment.

The process to follow is:

1 Start the **DATOSPIR MICRO** and select Maintenance from the Main screen.

Access the Equipment Check option and run all the suboptions, following the instructions on the screen.

2 Connect the equipment and the PC by series port, USB or Bluetooth.

3 Run the previously installed **W-20 Spirometry Software**, making sure that the DATOSPIR MICRO is selected in Configuration - Links and access the Configuration - Utilities - Download Data option.

The transferred information is saved in the DATA directory of the application, in the files:

STATUS.CSV Contains the errors detected
CALIBRA.CSV Contains the calibration data
CONFIG.CSV Contains the equipment customisation
PRUEBAS.CSV Contains the database tests
GRAFXxx.CSV Contains the graphs in Flow/Time mode

The files from the previous transfer are renamed with the extension **.OLD**

4 If you want to view the information of any of the files, load them using MICROSOFT EXCEL.

5 Load the files to your normal e-mail programme and send to the **SIBEL S.A. AFTER-SALES SERVICE or your Distributor** , who will analyse them and contact you to solve the problem presented.

If you do not have e-mail, you can print the data and send it by FAX.

4.2 PATIENT TEST MANAGEMENT IN THE PC

If you want ot view, print, manage and/or save the tests in the PC, you must have **W-20 Spirometry Software**.

The process to follow is:

1 Save the tests required in the equipment's internal Database.

2 Install the **W-20 Spirometry Software**, as detailed in its **User's Manual**.

3 Load the Database data from the PC using the W-20 Software **BATCH** option.

4 The screen shows a list of the tests transferred and you can select those to be imported to the **PC Database** selected in the W-20 Software Configuration option.

5 From then on, you can select, view or print any of the tests imported or transferred to the PC.

4.3 EXPORTING TESTS TO OTHER SYSTEMS

The DATOSPIR MICRO spirometer can export the tests saved previous to the **Internal Database** to other management systems in each hospital.

The equipment shows the information in **comma-delimited mode**, making it compatible with many different systems.

The information is available in the following files:

PRUEBAS. CSV Contains the database tests
PATIENTS.CSV Contains the database patients
GRAFxx. CSV Contains the graphs in Flow/Time mode

The graph file, as indicated, contains the graphs for each test in **Flow / Time** mode. If you want to display the graphs in **Volume / Time** or **Flow / Volume** mode in the new management system, the following aspects must be taken into account:

- The Flow signal with the turbine-type transducer is sampled at 50Hz.

- The ratio of the axes in the Volume/Time graph must be adjusted to 1 litre = 2 seconds.

- The ratio of the axes in the Flow/Volume graph must be adjusted to 2 l/s = 1 l

In the event of doubt or queries, contact the **SIBEL S.A. Technical Service** or your distributor, who will provide any further information you may require.

4.4 SPIROMETRY SOFTWARE W-20 FOR PC

See the **W-20 Spirometry Software User's Manual** for all related information.

5. TECHNICAL SPECIFICATIONS

The specifications given below are applicable in each case, depending on the model available, as indicated in detail in Section **1.3 SPIROMETER MODELS**.

5.1 TYPES OF TEST, FUNCTIONS AND PARAMETERS

FORCED VITAL CAPACITY FVC

Parameters:

- FVC (l) Forced Vital Capacity
- FEV.5 (l) Forced Expirometry Volume in 0.5 seconds
- FEV1 (l) Same in 1 second
- FEV3 (l) Same in 3 seconds
- FEV.5/FVC (%) Ratio
- FEV1/FVC (%) Ratio
- FEV3/FVC (%) Ratio
- FEV1/VC (%) Ratio
- PEF (l/s) Flow Apex
- FEF75%(*) (l/s) Maximum Expiratory Flow with 75% of FVC remaining in the lungs
- FEF50%(*) (l/s) Same, with 50% of FVC
- FEF75%(*) (l/s) Same, with 25% of FVC
- FEF25-75% (l/s) Forced mesoexpiratory flow
- FEF75-85% (l/s) Average flow between 75-85% of FVC
- FET25-75 (s) Time passed between 25-75% of FVC
- FET100 (s) Forced Expiratory Time
- FEF50/FIF50(*) (-) Ratio
- FEV1/FEV.5 (-) Ratio
- FEV1/PEF (-) Ratio

- FIF50%(*) (l/s) Maximum Inspiratory flow with 50% of FVC inspired
- FIVC (l) Forced Vital Inspiratory Capacity
- FIV1 (l) Forced Inspirometry Volume in 1 second
- FIV1/FIVC (%) Ratio
- FEV1/FIV1 (%) Ratio
- PIF (l/s) Inspiratory Flow Apex
- MTT (s) Mean Transit Time
- PEF/PIF (-) Ratio
- Vext (%) Volume extrapolated in relation to FVC
- MVVInd (l/min) Maximum indirector Voluntary Ventilation (30 x FEV1)

- FEV6 (l) Forced Expirometry Volume in 6 seconds
- FEV1/FEV6 (%) Ratio
- EPOC rate Parameter that depends on the number of cigarettes smoked a day, the age and FEV1. Indicates the risk of EPOC.
- Age of the Lung Parameter that depends on the height and FEV1. Indicates the equivalent age of the lung.

(*) According to ERS-ATS standardisation, parameters MEF25, MEF50 and MEF75 are replaced by FEF75, FEF50 and FEF25.

Diagnosis based on:

- Miller Quadrant
- Snider, Kory & Lyons

Percentage deviation in relation to values of reference

Standardised values of reference that can be selected from several standards

Patient's ID details

Atmospheric data on temperature, pressure and relative humidity

Graphs in FLOW / VOLUME and VOLUME / TIME

Warnings of manoeuvre compliance with ATS / ERS criteria

Saving of five manoeuvres from the same test

Acoustic and graphic indication of the start and end of each manoeuvre

SLOW VITAL CAPACITY

Parameters:

- VC (l) Slow vital capacity
- TV (l) Tidal volume
- ERV (l) Expiratory Residual Volume
- IRV (l) Inspiratory Residual Volume
- IC (l) Inspiratory Capacity
- Ti (s) Inspiratory time
- Te (s) Expiratory time
- Tt (s) Total time
- Ti/Tt (-) Ratio

Percentage deviation in relation to values of reference

Standardised values of reference that can be selected from several standards

Patient's ID details

Atmospheric data on temperature, pressure and relative humidity

Graphs in VOLUME / TIME mode

Saving of five manoeuvres from the same test

MAXIMUM VOLUNTARY VENTILATION

Parameters:

- MVV (l/min) Maximum Voluntary Ventilation
- Br./min (Br/min) Breathing frequency of MVV

Percentage deviation in relation to values of reference

Standardised values of reference that can be selected from several standards

Patient's ID details

Atmospheric data on temperature, pressure and relative humidity

Graphs in VOLUME/TIME mode

Saving of five manoeuvres from the same test

POST BRONCHIAL DILATION TEST

Same parameters and characteristics as in FVC

Several methods of comparison among PRE, POST and REF values

Superimposing of PRE and POST graphs

SpO_2 PULSE OXIMETRY

The DATOSPIR MICRO allows for specific or long-term measurements lasting for 8 hours.

Parameters:

- CT90 % of time in which SpO_2 is below 90%
- CT80 % of time in which SpO_2 is below 80%
- CT70 % of time in which SpO_2 is below 70%

- IDH-4 Desaturation index (>= 4%) per hour
- IDH-3 Desaturation index (>= 3%) per hour
- IDH-2 Desaturation index (>= 2%) per hour
- Maximum SpO_2 Maximum Saturation value
- Average SpO_2 Average Saturation value
- Minimum SpO_2 Minimum Saturation value
- Std. SpO_2 Standard Saturation value
- Maximum PR Maximum pulse rate value
- Average PR Average pulse rate value
- Minimum PR Minimum pulse rate value
- Std. PR Standard pulse rate deviation
- Test Time Useful test time (when the finger clip is disconnected is not considered)

CALIBRATION

Calibration programme for dynamic tests with syringe of 1 to 6 litres in volume.

Register of the latest calibrations

Where required, calibration warning

CUSTOMISATION PROGRAMME

User-selected STANDARD configuration

Customisation of the language, printer and report heading, etc.

Spirometry customisation
- Parameters of reference
- Observed parameters
- Graph selection
- Diagnosis selection
- Report customisation ...

Pulse oximetry customisation

INTERNAL DATABASE

Saving of spirometric and pulse oximetry tests.

Two types of database according to their storage capacity

CLOCK-CALENDAR

Hour-Minute-Second

Day-Month-Year

5.2 MEASURING SYSTEM

TYPE OF TRANSDUCER

Turbine-type transducer with axial-type two-way volumetrics, with opto-electronic rotary sensor that is detachable for cleaning and sterilisation. Rotation is made on saphire bearings for high reproduceability and duration.

RANGES AND MEASUREMENTS

Turbine

- Measurement Scale (BTPS)
  Flow (l/s) 0 to ± 16
  Volume (l) 0 to 10
- Dynamic flow resistance
  kPa/l/s < 0.122 to 14 l/s
- Precision of measurements (BTPS)
  Volume (the highest) 3% or 50 ml
  Flow (the highest) 5% or 150 ml/s
  Time-related precision 0,5%
- Resolution in volume (ml) < 6
- Sampling frequency (Hz) 25
- Turbine lifetime 600 disinfections or 3 years

SpO_2 and Pulse

		SpO_2 (%)	Pulse (BPM)
Measurement Range		0-100	0-250
Resolution		1	1
Precision	70 to 100	+/- 2	+/- 1 or 3% (the highest)
	< 70	Not specified	

5.3 MICRO CONTROLLER

System micro controller:

- Hitachi H8S2144

Volume accumulation time:

- Five FVC curves with a maximum of 25 seconds each
- Five VC curves with a maximum of 45 seconds each
- Five MVV curves with a maximum of 15 seconds each

Start FVC expiration:

- Using the retrograde extrapolation method

End FVC expiration:

- When the volume accumulated in the last second is below 0.025 litres

FVC test selection:

- According to the criterion of the maximum sum of FVC+FEV1 or depending on the operator

Parameter selection:

- FVC and FEV1, the two with the highest value of the tests saved. Remaining parameters of the selected test, with the highest sum being recommended.

Keypad:

- All instructions, data, etc. transmitted by the operator to the microprocessor involve a keypad with silicon keys (Model A) or a touch screen (Models B and C).

Comunicacións channel:

- RS 232C
- USB 2.0
- Bluetooth 2.0.

Printer:

- Compatible with HP-PCL black and white or color printers.

5.4 PRESENTATION OF DATA

LCD (Liquid Crystal Display) of 2x16 (Model A) or high resolution touch screen LCD (Liquid Crystal Display) with array of 240 x 160 points (Models B and C)

By external printer

By PC with the corresponding software

5.5 TEMPERATURE SENSOR

Internal temperature sensor from 0 to 50 °C ± 2 °C

5.6 GENERAL DATA

Relative humidity:

- Less than 75% (without condensation)

Barometric pressure:

- Between 430 and 800 mmHg (approx. 4500 to -400 metres altitude)

Temperature:

- Storage, between 0 and 60 °C
- Working, between 10 and 40 °C

Applicable standards:

- Spirometry (ATS/ERS, SEPAR)
- Safety (EN 60601.1, EN 60601.1.1)
- Electro-magnetic Compatibility (EN 60601.1.2). See Appendix 1
- Quality (EN 13485, ISO 9001:2000)
- Spirometers for peak espiratory flow (UNE EN 13826:2004)
- Bluetooth Module
  - Compliance with Standard 2.0
  - Class II
  - CE and FCC Certificate.

Power supply:

- 1.5 V battery (alkaline recommended) or 1.2 NiMh battery (recommended > 2200mAh).

Power:

- Below 400 mW

Size:

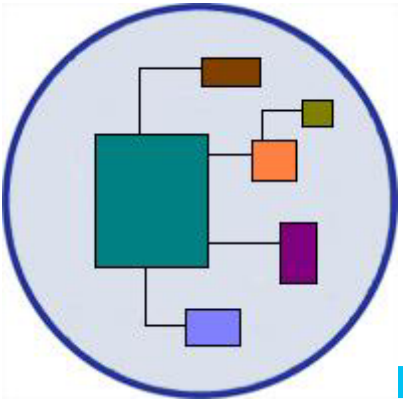
- 153.5 x 80 x 52 mm

Weight:

- 250 g

Equipment lifetime:

- 10 years



6. OPERATING PRINCIPLES

The **DATOSPIR MICRO** spirometer is a piece of equipment that acquires physical signals and processes the information provided by the signal related to the pulmonary function. For processing purposes, physical must be changed to electrical. The units responsible for this change are called transducers. The **DATOSPIR MICRO** has a Turbine-type transducer.

The turbine transducer performs transduction in two stages: The volume to be measured crosses the turbine and prints its rotation that is proportional to that volume. This rotation is detected by the interrupting of a beam of infrared light, the sensor of which converts the light received into a digital-type electrical signal.

6.1 TURBINE

The turbine is axial with two stators in the form of a propeller and a rotor made up of a flat, rectangular blade. The shape of the stators means that the air flow passing turns, which makes the blade turn. The turbine operates based on the Fluid Mechanics theory and, more specifically, the Machine Turbo theory. Applied to this case, the angle at which the rotor turns is directly proportional to the fluid volume crossing the turbine and the proportionality constant depends on its shape.

6.2 TURBINE ROTATION SENSOR

The turbine rotation sensor consists of three pairs of emitting diodes and an infrared (invisible) photo-transistor that, appropriately positioned, detect the rotation and its direction. The number of times the beam is interrupted is equivalent to an accumulated angle of rotations and, therefore, the voluem of air to have crossed the turbine. The photo-transistor provides a digital electrical signal that represents the times the beam of light is interrupted and is directly acquired by the microprocessor.

6.3 MICROPROCESSOR

PHYSICAL DESCRIPTION

The microprocessor system is made up of a series of electronic devices that save, manage, receive and send data. In general terms, it is divided into:

- Basic hardware control programme (BIOS) residing in the internal Flash of the Micro controller (128 KBytes).

- Spirometry and equipment management programme and test database residing in the 2 MByte FLASH memory.

- Non-volatile 512 KByte RAM memory to save the equipment configuration, status variables and calibration database.

- Central Processing Unit (CPU).

- Communications controller (Series, USB and Bluetooth) with the outside.

- Clock - Calendar - Alarm.

PROGRAMME

The control programme has been developed in assembler and in top level C language to ensure very fast time control and a structured programme. It is divided into two parts: the Bios in internal Flash and the application in external Flash.

MEMORY

The storage capacity for temporary data, for the customised equipment configuration and for the calibration database is 512 KB in non-volatile RAM. The test database has a maximum capacity of 1 MByte.

CPU

This device manages and runs the process that is coded into the data forming the programme. The Renesas H8S2144 micro controller is used as a CPU.

CONTROLLERS

These are responsible for transferring data between the CPU and the other devices, such as the keypad, the screen and the printer. They form part of the integrated micro controller circuit, except for the RS-232 series communications channel interface and the screen controller.

QUALITATIVE DESCRIPTION

The control programme is responsible for ensuring the spirometry signals are handled in line with the applicable standards, particularly the calculation of:

- Identification of the start of expiration
The start of the test is determined by the filling of a maximum level of flow of approximately 100ml/s, although the immediately inferior values are not rejected.

- Retrograde extrapolation
The start of the FVC manoeuvre is established through retrograde extrapolation according to A.T.S. criteria

- Identification of the end of inspiration
The end of the FVC manoeuvre is established according to A.T.S. criteria, i.e. when the volume accumulated in the last second is below 30ml.

- Calibration programme

Turbine

Any ageing of or accumulated dirt in the turbine transducer may lead to imprecise measurements. To ensure the turbine measures correctly, the system includes a simple checking procedure based on measuring the known volume of a calibration syringe.

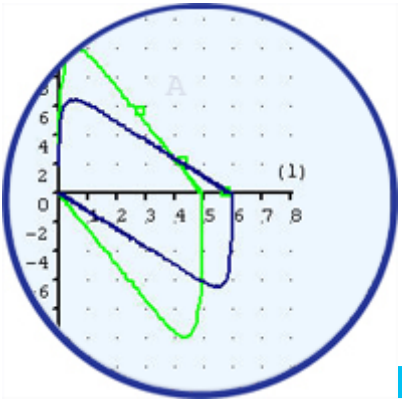
6.4 PULSE OXIMETER

The DATOSPIR MICRO includes an electronic module exclusively for taking Oxygen Saturation and Pulse Rate samples.

This module is powered by the motherboard and communicates with it through a specific series port.

The pulse oximetry measurement principle is based on the different absorption of certain wave lengths (red and infrared) through the arteries, depending on the amount of Haemoglobin transported by the red cells.

The wave lengths used are 660 nm for red and 910 nm for infrared.



7. SPIROMETRY TECHNIQUE

7.1 PROCEDURE

The following is an extract from the "**STANDARD FOR FORCED SPIROMETRY". SEPAR Recommendations, No. 1**.

"Forced spirometry will be performed with the patient seated upright, with the nose occluded by clips. The technician will rest his hand on the patient's shoulder to prevent him from leaning forwards during expiration. The mouthpiece will keep its shape to prevent the hole from being reduced due to biting during forced expiration. Soft mouthpieces must be shortened to increase their consistency. Spirometry always involves a minimum of three forced expiration manoeuvres and a maximum of eight when not considered suitable. Exceeding this limit leads to the needless tiring of the patient and a loss of the technician's time"

"To assess the spirometry performed lying down, remember that under these conditions the data obtained is approximately 10% below those obtained when the patient is seated. In patients with a diaphragmatic or neuromuscular pathology, the difference between the two positions may be up to 40-60%, making the observation a useful piece of data to assess the repercussions of this pathology."

"When working with a pneumotachometer, the manoeuvre may be exclusively reduced to maximum expiration from the maximum inspiration position. The correction of a manoeuvre will be judged by its start, its progress and its completion, observing the patient and the tracing of the graph. The start must produce a clean, sudden deflection, the progress itself will draw a gentle, upwards concave curve without rectifications and the end must be asymptotic and not perpendicular or sudden (Volume/Time). The expired volume measured during a forced manoeuvre will be influenced by the selecting of its starting point. This means that a manoeuvre starting criterion must be chosen and maintained consistently. The so-called retrograde extrapolation is the most consistent and accepted method by European and American laboratories and will be chosen, unless other methods are shown

to be similar or to have equivalent results. The volume extrapolated using this method must be below 5% of the vital capacity or 150 ml, without exceeding either of the two criteria."

"To ensure good spirometry, the technician will pay particular attention to ensure that the patient has made the utmost effort, that the start has been good and that no coughing or Valsava's manoeuvre due to glottis closure has occurred. Special attention must be paid to preventing expiration from ending too soon, which would be detected in the end of the curve, which would be too perpendicular to the horizontal base line. Sometimes the patient inadvertently partially obstructs the mouthpiece with his tongue or false teeth. It is essential that the best two expirations from the best three acceptable curves do not vary by more than 200 ml of FVC or FEV1. The best effort cannot only be determined by merely inspecting the spirometric curve but also by checking the measurements to determine the maximum values. The independent selection of FVC and FEV1 sometimes causes greater variability, as factors such as learning, tiredness or bronchial spasms caused by expiration come into play. The best FEV1 does not have to be rejected when the manoeuvre from which it originates has ended prematurely. However, FEF25-75% is influenced by the vital capacity of the curve chosen. Falsely high values may be recorded if a manoeuvre with a shortened or lower vital capacity than the real vital capacity of the patient has been chosen. It seems that the most practical criterion is to choose the manoeuvre containing the FVC and FEV1 with the highest sum among the three chosen for calculation."

7.2 CALIBRATIONS

"As well as the calibration procedures included by the manufacturer in the appliance to quickly check the working order of the basic pneumotachometer circuits and mechanisms, it must be possible to check the appliance through external signals. These signals must be as similar as possible in terms of flows, volumes and times to the biological signal for which the instruments were designed, i.e. forced expiration. This is not always possible,

although at least one of the elements of the biological signal, the volume or the flow, must be reproduced together or separately. Along these lines, the syringes holding several litres provide a suitable signal and the flow generators can be used to assess the precision and errors in flow measurement. Among the most suitable calibration appliances is the so-called explosive decompressor, which consists of a 4 or 5-litre pressurised, one-atmosphere chamber fitted with a fast opening for the sudden expulsion of an identical volume to that of the chamber. This simulates the forced expiration of a person and, with suitable resistances at different levels of obstruction fitted to the output tube, the signal is similar to that of a patient with slight, moderate or severe obstruction in the air flow. Hence, the volume and flow measurement can be examined. If this is not possible, the working order of the appliance must be checked using «control individuals». i.e. people close to the laboratory and whose cooperation is attainable, to carry out correct spirometry with easy and scarce variability (Table I), so that their spirometry can be regularly reproduced and compared with the previous data. Hence, errors can be detected that would have to be significant in size, as the variability of spirometry itself prevents small differences in the measuring of volume and flow from being detected (see Table I)."

"Under normal working conditions, calibration using the volume signal provided by a manual syringe will be performed on a daily basis. The signal provided by the syringe must be produced with different pulses to check whether the flow reading remains steady, as the appliance must always integrate the signal in the same volume - that provided by the syringe signal - whatever the suddenness of the injection manoeuvre, with the upper limit of the flow range precisely measured (close to the real value) by the instrument in question not being exceeded. Calibration with a dynamic signal produced by the explosive decompressor or the measuring of spirometry on control individuals, as mentioned above, may be performed relatively less often. It is wise to perform calibration using the decompressor every fortnight in the case of pneumotachometers. Given that spirometry with control individuals

is more complicated and less accessible, this procedure cannot be performed more often than every month or whenever the appliance is thought to be malfunctioning."

"Table I.» Variability of spirometry in healthy patients

Variation coefficient (%)		
Variables	Age: 6-20*	20-70**
FVC	1.9	2.2
FEV1	2.2	2.2
FEF25-75%	6.5	4.8
FEF50 %FVC***	5.3	4.7

* Values corresponding to 33 healthy volunteers
** Values from 20 healthy adults"
***According to ATS/ERS standardisation, parameters MEF50 is replaced by FEF50.

7.3 VALUES OF REFERENCE FOR FORCED SPIROMETRY «SEPAR»

The DATOSPIR MICRO spirometer includes different tables of reference that may be selected using the Customisation programme.
Below are the equations corresponding to the SEPAR and "ECCS.93" references. Should you require any other table, please consult SIBEL S.A.

"Multi-centre study in Barcelona

Variable	Sex	Equation (Age 6-20)	R	SEE
FVC	M	0.02800T+0.03451P+0.05728E-3.21	0.947	0.443
	F	0.03049T+0.02220P+0.03550E-3.04	0.935	0.313
FEV1	M	0.02483T+0.02266P+0.07148E-2.91	0.945	0.378
	F	0.02866T+0.01713P+0.02955E-2.87	0.940	0.263
*FEV1/FVC%	M	0.593E - 0.113P + 81.60		
	F	0.026T + 82.60		
FEF 25-75%	M	0.038T + 0.140E - 4.33	0.832	0.796
	F	0.046T + 0.051E - 4.30	0.789	0.651
PEF	M	0.075T + 0.275E - 9.08	0.907	1.073
	F	0.073T + 0.134E - 7.57	0.879	0.831
FEF 50%FVC(*)	M	0.017T + 0.157E + 0.029P - 2.17	0.856	0.811
	F	0.046T + 0.067E - 4.17	0.803	0.669
FEF 75%FVC(*)	M	0.024T + 0.066E - 2.61	0.760	0.562
	F	0.027T + 0.032E - 2.68	0.709	0.507

Variable	Sex	Equation (Age 20-70)	R	SEE
FVC	M	0.0678T - 0.0147E - 6.05	0.72	0.530
	F	0.0454T - 0.0211E - 2.83	0.75	0.403
FEV1	M	0.0499T - 0.0211E - 3.84	0.75	0.444
	F	0.0317T - 0.0250E - 1.23	0.82	0.307
*FEV1/FVC %	M	- 0.1902E + 85.58		
	F	- 0.224E - 0.1126P + 94.88		
FEF 25-75%	M	0.0392T - 0.0430E - 1.16	0.55	1.000
	F	0.0230T - 0.0456E + 1.11	0.70	0.680
PEF	M	0.0945T - 0.0209E - 5.77	0.47	1.470
	F	0.0448T - 0.0304E + 0.35	0.47	1.040
FEF 50%FVC(*)	M	0.0517T - 0.0397E - 2.40	0.47	1.300
	F	0.0242T - 0.0418E + 1.62	0.56	0.925
FEF 25%FVC(*)	M	0.0190T - 0.0356E - 0.14	0.63	0.620
	F	0.02T-0.031E-0.0062P-0.21	0.76	0.405
*FEV1/PEF	M	6.64		
	F	7.77		
*FEV1/FEV0.5	M	1.45		
	F	1.50		
*FEF50/FIF50(*)	M	0.66		
	F	0.88		
*PEF/PIF	M	1.39		
	F	1.42		
*FEV1/FIV1	M	0.80		
	F	0.89		

M: male; F: female
R: multiple correlation coefficient
SEE: typical estimate error
T: height (cm), P: weight (Kg), E: age (years).»

The parameters with an asterisk * are not listed in the SEPAR standard.

7.4 VALUES OF REFERENCE FOR FORCED SPIROMETRY «ECCS.93»

(Standardized Lung Function Testing, Official Statement of the European Respiratory Society, Luxembourg 1993)

Variable	Sex	Equation (Age 18-70)	RSD	1.64RSD
FVC	M	5.76H - 0.026A - 4.34	0.61	1.00
	F	4.43H - 0.026A - 2.89	0.43	0.71
FEV1	M	4.30H - 0.029A - 2.49	0.51	0.84
	F	3.95H - 0.025A - 2.60	0.38	0.62
FEV1/FVC %	M	- 0.18A +87.21	7.17	11.80
	F	- 0.19A +89.10	6.51	10.70
FEF 25-75%	M	1.94H - 0.043A + 2.70	1.04	1.71
	F	1.25H - 0.034A + 2.92	0.85	1.40
PEF	M	6.14H - 0.043A + 0.15	1.21	1.99
	F	5.50H - 0.030A - 1.11	0.90	1.48
FEF 75%FVC(*)	M	5.46H - 0.029A - 0.47	1.71	2.81
	F	3.22H - 0.025A + 1.60	1.35	2.22
FEF 50%FVC(*)	M	3.79H - 0.031A - 0.35	1.32	2.17
	F	2.45H - 0.025A + 1.16	1.10	1.81
FEF 25%FVC(*)	M	2.61H - 0.026A - 1.34	0.78	1.28
	F	1.05H - 0.025A + 1.11	0.69	1.13

M: male; F: female
H: height (m); A: age (years).
RSD: (Residual Standard Deviation)

(*) According to ATS/ERS standardisation, parameters MEF25, MEF50 and MEF75 are replaced by FEF75, FEF50 and FEF25.

Between the ages of 18 and 25, 25 is replaced in the equations.

IMPORTANT NOTE:

The DATOSPIR MICRO spirometer allows for an ETHNIC FACTOR to be entered, which modifies the values of reference for certain groups of the population. This factor ranges from 80 % to 120 % of the values of reference, where 100 % is the value according to each table.

7.5 OTHER VALUES OF REFERENCE

Based on Separ and Ceca references, the spirometer has the following references:

- Knudson
- Crapo
- Zapletal
- Morris
- Austria
- Gutierrez (Chili)
- Castro-Brazil
- Polgar / Weng
- Hankinson (NHNES III)
- Perez Padilla (Mexico)
- A.J. Cruz (Mexico)
- Golshan (Iran)

8. UPKEEP, PREVENTATIVE AND CORRECTIVE MAINTENANCE

Like any equipment, particularly if for medical applications, the **DATOSPIR MICRO** spirometer requires upkeep and maintenance aimed firstly at the safety of patients, operators and the environment, and secondly, at ensuring the reliability and precision of the functions for which it has been developed.
All this leads to a series of routines that must be completed.

8.1 UPKEEP

Upkeep is aimed at ensuring the correct working order of the equipment. The person undertaking it requires no special technical skills except knowledge of the functions and handling of the equipment.
The equipment user himself must normally perform this. The operations to be completed are as follows:

CLEANING THE TURBINE TRANSDUCER

Given that the turbine is the part exposed directly to the patient, it must be kept in perfect physical and hygienic conditions. To do so, proceed as follows:

1 The turbine is removed from the equipment housing by pressing slightly so that is comes away from its fixtures.

2 Wash the turbine with water and soap, avoiding solvents or abrasive substances that may damage the components. Given that its reliability depends on the condition of the turbine, make sure it is not damaged.

3 Once rinsed, avoid salt deposits by rinsing again with distilled water.

4 You can then leave it to dry at room temperature.

5 Reassemble the turbine in the housing.

Top level disinfection:
If you suspect microbial contamination, use one of the more complex antiseptic solutions or sterilisation procedures. For example, replace Step **2** by submerging it in a glutaraldehyde solution (or similar) for 10 minutes (follow the manufacturer's instructions).

PRECAUTION
DO NOT EXPOSE THE TURBINE TO TEMPERATURES OF OVER 60 °C OR BELOW 0 °C. DO NOT USE SOLVENTS OR OTHER SIMILAR SUBSTANCES FOR CLEANING AS THEY MAY DAMAGE IT.

SPIROMETER

The spirometer is cleaned gently with a dry cloth or a cloth dampened slightly with soapy water, with any remains of water then being dried. Pay special attention to ensure no liquid enters the inside or connectors and connections.
Do not use abrasive substances or solvents.

WARNING
Remove the batteries from their compartment before cleaning.

PULSE OXIMETRY FINGER CLIP

Although unlikely, the organisms can also be transmitted by pulse oximetry. Therefore, the pulse oximeter finger clip should be washed with each patient change using either soapy water or a glutaraldehyde solution (Instrunet type).

8.2 PREVENTATIVE MAINTENANCE

Preventative maintenance consists of any actions aimed at keeping the equipment in a good state of repair.

Four types of preventative maintenance are established:

1 Every time it is started, the equipment will check certain parts.

2 A second type, which can be performed by the user, consists of the regular monitoring of the appearance of the different connections and other external parts of the equipment. Check that all connections are perfectly connected, that no cable and/or connector or any other element is broken or damaged.

In the event of detecting any problem that the user cannot solve, contact the **SIBEL S.A. After-Sales Service or your distributor** to review or repair it.

3 The user can access the **Maintenance Programme** to adjust and/or check any parts of the equipment, as indicated in detail in the corresponding section.

4 A fourth type consists of a general technical check of the safety systems, adjustments and functions, etc. forming the equipment.

THIS TECHNICAL CHECK WILL BE PERFORMED EVERY YEAR and in line with the **DATOSPIR MICRO** Verification and Adjustment Procedure available from the manufacturer. This type of operation must be carried out by skilled technical staff from the hospital's maintenance department or from the distributor's or manufacturer's technical service.

On all accounts, **SIBEL S.A.** , as the manufacturer, must provide written authorisation, for at least the guarantee period, for the corresponding technical personnel to carry out said maintenance and will not be held liable under any circumstances for any damage, malfunction, etc. that may arise as a result of defective maintenance by people not belonging to **SIBEL S.A.**

8.3 CORRECTIVE MAINTENANCE

Corrective maintenance consists of leaving equipment that has stopped working and must be repaired, due to malfunctioning or misuse, in a good state of repair.

Where a fault is detected in the equipment which prevents it from being used normally, contact the **SIBEL S.A**. After-Sales Service and specify the problem in as much detail as possible.

APPENDIX 1

ELECTROMAGNETIC COMPATIBILITY

Guidance and manufacturer's declaration – electromagnetic emissions		
Datospir Micro is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - Guidance**
RF (Radiated) emissions CISPR 11 (EN 55011)	Group 1	Datospir Micro uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF (Conducted) emissions CISPR 11 (EN 55011)	Not applicable	Datospir Micro works with batteries / DC USB power.
Harmonic emissions EN-IEC 61000-3-2	Not applicable	Datospir Micro works with batteries / DC USB power.
Voltage fluctuations / Flicker emissions EN-IEC 61000-3-3	Not applicable	Datospir Micro works with batteries / DC USB power.

Guidance and manufacturer's declaration – electromagnetic immunity			
Datospir Micro is intended for use in the electromagnetic environment specified below. The costumer or the user of Datospir Micro should assure that it is used in such an environment.			
Immunity test	**EN-IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – Guidance**
Electrostatic discharge (ESD) EN-IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst EN-IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV Not applicable	DC USB +5V power. The input/output line cables are shorter than 3 meters long.
Surge EN-IEC 61000-4-5	±1 kV differential ±2 kV common mode	Not applicable Not applicable	Datospir Micro works with batteries / DC USB power. The input/output line cables are shorter than 3 meters long.
Voltage dips, short interruptions and voltage variations on power supply input lines EN-IEC 61000-4-11	<5 % Ut (>95 % dip in Ut) for 0.5 cycle 40 % Ut (60 % dip in Ut) for 5 cycles 70 % Ut (30 % dip in Ut) for 25 cycles <95 % Ut (>5 % dip in Ut) for 5 seconds	Not applicable	Datospir Micro works with batteries / DC USB power.
Power frequency (50 / 60 Hz) magnetic field EN-IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial of hospital environment.

Guidance and manufacturer's declaration – electromagnetic immunity

Datospir Micro is intended for use in the electromagnetic environment specified below. The costumer or the user of Datospir Micro should assure that it is used in such an environment.

Immunity test	EN-IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment should be used no closer to any part of Datospir Micro, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF EN-IEC 61000-4-6	3 Vrms 150KHz to 80 MHz outside ISM bands[c]	3 Vrms	$d = \left[\frac{3.5}{E}\right]\sqrt{P}$ 80 MHz to 800 MHz
Radiated RF EN-IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = \left[\frac{3.5}{E}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E}\right]\sqrt{P}$ 800 MHz to 2.5 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range [b]. Interference may occur in the vicinity of equipment marked with the following symbol:

Note 1. At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which Datospir Micro is used exceeds the applicable RF compliance level above, Datospir Micro should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such reorienting or relocating Datospir Micro.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m

[c] ISM bands: 6.765 - 6.795 MHz, 13.553 - 13.567 MHz, 26.957 - 27.283 MHz, 40.66 - 40.70MHz

Recommended separation distances between portable and mobile RF communications equipment and Datospir Micro

Datospir Micro is intended for use in an electronic environment in which radiated RF disturbances are controlled. The costumer or the user of Datospir Micro can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and Datospir Micro as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum output power of transmitter W	**Separation distance according to frequency of transmitter**	
	80 MHz to 800 MHz $d = \left[\frac{3.5}{3}\right]\sqrt{P}$	**800 MHz to 2.5 GHz** $d = \left[\frac{7}{3}\right]\sqrt{P}$
0.01	0.12	0.23
0.1	0.37	0.74
1	1.17	2.33
10	3.69	7.38
100	11.67	23.33

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1 At 800 MHz, the separation distance for the higher frequency applies.

Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absortion and reflection from structures, objects and people.

APPENDIX 2

COMPLIANCE WITH THE DATA PROTECTION ACT (LOPD)

COMPLIANCE WITH THE DATA PROTECTION ACT. DIRECTIVE 95/46/EC.

Requirements specifically affecting the use of the DATOSPIR MICRO Spirometer

This section seeks to ensure user compliance with the current data protection legislation in relation to the use of this equipment.

A brief description is given as to how the **DATOSPIR MICRO** Spirometer must be handled to comply with the requirements of this act.

IMPORTANT WARNING

- According to current legislation, the user of this equipment is the only party responsible for saving and processing the details of his patients according to the Law.
- Observance of the recommendations included in this section under no circumstances guarantees the full adaptation of the user's activity to the data protection regulation.

Configuration of the DATOSPIR MICRO Protection

The **DATOSPIR MICRO** spirometer has an equipment protection option that uses a password or pin.
This option is user-configurable and seeks to prevent access by unauthorised people to the equipment and, more specifically, to the private data it contains.
To comply with current legislation, users must enable this option and configure their pins. They will be held responsible for providing this pin to the authorised people.

Thus, when the spirometer is started, a pin will be requested and the equipment locked where this pin is entered erroneously three times.
On restarting the equipment, the unlock code (PUK) provided by the manufacturer upon purchasing the equipment will be requested. If this code is not available, the equipment will remain locked.

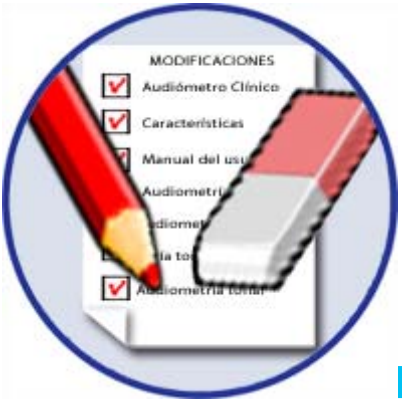
Other important issues

- Printing documents:

In the event of saving paper printouts containing patient details, these documents must be properly stored so that only duly authorised personnel have access to them. Furthermore, in the event of users deciding to dispose of the printed documents, their effective physical destruction must be ensured to avoid unauthorised access thereto.

- Data transmission:

The **DATOSPIR MICRO** spirometer can transmit files containing patient details via PC connection so that work can be subsequently carried out on them using the **W20 Spirometry Software**. This software is also compliant with the Data Protection Act, as explained in the W20 Spirometry Software User's Manual.



APPENDIX 3

MODIFICATIONS